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(74) Agents: **CONDINO, Debra, D.** et al.; Edwards Life-  
sciences LLC, One Edwards Way, Irvine, CA 92614 (US).

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(71) Applicant: **EDWARDS LIFESCIENCES CORPORATION** [US/US]; One Edwards Way, Irvine, CA 92614 (US).

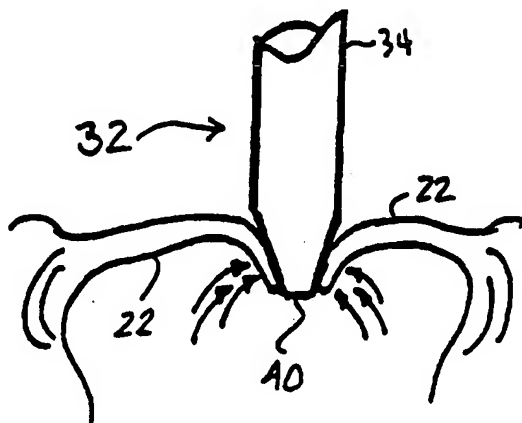
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(72) Inventors: **ALLEN, William, J.**; 4 Oxford Road, Milford, CT 06460 (US). **BACHMAN, Alan**; 4 Oxford Road, Milford, CT 06460 (US). **REED, Scott**; 4 Oxford Road, Milford, CT 06460 (US). **ADAMS, Ray**; 4 Oxford Road, Milford, CT 06460 (US). **STECKEL, Robert, R.**; 4 Oxford Road, Milford, CT 06460 (US).

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(54) Title: **MINIMALLY INVASIVE MITRAL VALVE REPAIR METHOD AND APPARATUS**



(57) Abstract: The present invention is directed to an apparatus and method for the stabilization and fastening of two pieces of tissue. A single device may be used to both stabilize and fasten the two pieces of tissue, or a separate stabilizing device may be used in conjunction with a fastening device. The stabilizing device may comprise a probe with vacuum ports and/or mechanical clamps disposed at the distal end to approximate the two pieces of tissue. After the pieces of tissue are stabilized, they are fastened together using suture or clips. One exemplary embodiment of a suture-based fastener comprises a toggle and suture arrangement deployed by a needle, wherein the needle enters the front side of the tissue and exits the blind side. In a second exemplary embodiment, the suture-based fastener comprises a needle connected to a suture. The needle enters the blind side of the tissue and exits the front side. The suture is then tied in a knot to secure the pieces of tissue. One example of a clip-based fastener comprises a spring-loaded clip having two arms with tapered distal

ends and barbs. The probe includes a deployment mechanism which causes the clip to pierce and lockingly secure the two pieces of tissue.

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## **MINIMALLY INVASIVE MITRAL VALVE REPAIR METHOD AND APPARATUS**

### **CROSS REFERENCE TO A RELATED PATENT APPLICATION**

Priority is herewith claimed under 35 U.S.C. §119(e) from copending Provisional Patent Application No.: 60/161,296, filed October 21, 1999, entitled "Minimally Invasive Mitral Valve Repair Method And Apparatus". The disclosure of this Provisional Patent Application is incorporated by reference herein in its  
5 entirety.

### **FIELD OF THE INVENTION**

The present invention relates to the repair of heart valves, and, more particularly, to methods and apparatuses for the repair of heart valves by fastening the valve leaflets together at their coapting edges.

### **10 BACKGROUND OF THE INVENTION**

In vertebrate animals, the heart is a hollow muscular organ having four pumping chambers: the left and right atria and the left and right ventricles, each provided with its own one-way outflow valve. The natural heart valves are identified as the aortic, mitral (or bicuspid), tricuspid and pulmonary valves. The  
15 valves separate the chambers of the heart, and are each mounted in an annulus therebetween. The annuluses comprise dense fibrous rings attached either directly or indirectly to the atrial and ventricular muscle fibers. The leaflets are flexible collagenous structures that are attached to and extend inward from the annuluses to meet at coapting edges. The aortic and tricuspid valves have three leaflets, while  
20 the mitral and pulmonary valves have two.

Various problems can develop with heart valves, for a number of clinical reasons. Stenosis in heart valves is a condition in which the valves do not open properly. Insufficiency is a condition which a valve does not close properly. Repair or replacement of the aortic or mitral valves are most common because they  
25 reside in the left side of the heart where pressures and stresses are the greatest. In a valve replacement operation, the damaged leaflets are excised and the annulus sculpted to receive a replacement prosthetic valve.

In many patients who suffer from valve dysfunction, surgical repair (i.e., "valvuloplasty") is a desirable alternative to valve replacement. Remodeling of the valve annulus (i.e., "annuloplasty") is central to many reconstructive valvuloplasty procedures. Remodeling of the valve annulus is typically accomplished by  
5 implantation of a prosthetic ring (i.e. "annuloplasty ring") to stabilize the annulus and to correct or prevent valvular insufficiency that may result from a dysfunction of the valve annulus. Annuloplasty rings are typically constructed of a resilient core covered with a fabric sewing ring. Annuloplasty procedures are performed not only to repair damaged or diseased annuli, but also in conjunction with other  
10 procedures, such as leaflet repair.

Mitral valve regurgitation is caused by dysfunction of the mitral valve structure, or direct injury to the mitral valve leaflets. A less than perfect understanding of the disease process leading to mitral valve regurgitation complicates selection of the appropriate repair technique. Though implantation of  
15 an annuloplasty ring, typically around the posterior aspect of the mitral valve, has proven successful in a number of cases, shaping the surrounding annulus does not always lead to optimum coaptation of the leaflets.

More recently, a technique known as a "bow-tie" repair has been advocated. The bow-tie technique involves suturing the anterior and posterior  
20 leaflets together in the middle, causing blood to flow through the two side openings thus formed. This process was originally developed by Dr. Ottavio Alfieri, and involved placing the patient on extracorporeal bypass in order to access and suture the mitral valve leaflets.

A method for performing the bow-tie technique without the need for bypass  
25 has been proposed by Dr. Mehmet Oz, of Columbia University. The method and a device for performing the method are disclosed in PCT publication WO 99/00059, dated January 7, 1999. In one embodiment, the device consists of a forceps-like grasper device that can be passed through a sealed aperture in the apex of the left ventricle. The two mitral valve leaflets meet and curve into the left ventricular  
30 cavity at their mating edges, and are thus easy to grasp from inside the ventricle. The mating leaflet edges are grasped from the ventricular side and held together, and various devices such as staples are utilized to fasten them together. The teeth of the grasper device are linearly slidable with respect to one another so as to align

the mitral valve leaflets prior to fastening. As the procedure is done on a beating heart, and the pressures and motions within the left ventricle are severe, the procedure is thus rendered fairly skill-intensive.

There is presently a need for an improved means for performing the bow-tie technique of mitral valve repair.

#### **SUMMARY OF THE INVENTION**

The present invention provides a number of devices and methods for fastening or "approximating" tissue pieces together. The term "tissue pieces" is to be understood to mean discrete pieces that may be straight, curved, tubular, etc., so long as the pieces are initially disconnected. For example, many of the embodiments of the invention disclosed herein are especially useful for joining two leaflets of a heart valve. The coapting edges of the leaflets thus constitute the "tissue pieces." In other contexts, the invention can be used to anastomose two vessels, either end-to-end, in a T-junction, or otherwise. In these cases, the two vessels define the "tissue pieces." One specific application of using the invention to perform an anastomosis is in a coronary artery bypass graft (CABG) procedure. Another example of an application of the present invention is in wound closure, wherein the facing edges of the wound are joined. In sum, the present invention in its broadest sense should not be construed to be limited to any particular tissue pieces, although particular examples may be shown and disclosed.

The present invention includes a number of devices and method for both stabilizing the tissue pieces to be joined, and fastening them together. Some embodiments disclose only the stabilizing function, others only the fastening function, and still other show combination stabilizing and fastening devices. It should be understood that certain of the stabilizing devices can be used with certain of the fastening devices, even though they are not explicitly shown in joint operation. In other words, based on the explanation of the particular device, one of skill in the art should have little trouble combining the features of certain of two such devices. Therefore, it should be understood that many of the stabilizing and fastening devices are interchangeable, and the invention covers all permutations thereof.

Furthermore, many of the fastening devices disclosed herein can be

deployed separately from many of the stabilizing devices, and the two can therefore be deployed in parallel. Alternatively, and desirably, however, the fastening and stabilizing functions are performed with one device.

The stabilizing and fastening devices of the present invention can be  
5 utilized in either standard open surgical procedures, endoscopic procedures, or percutaneous procedures. In one embodiment the devices can be delivered through an open chest either transapically or transatrially. In another embodiment, the stabilizing and fastening devices can be introduced through an incision performed over the roof of the left atrium. In yet another embodiment the devices can be  
10 delivered into the left ventricle through the right chest via a thoroscope. The devices can also be delivered percutaneously, via a catheter or catheters, into the patient's arterial system (e.g. through the femoral or brachial arteries). Other objects, features, and advantages of the present invention will become apparent from a consideration of the following detailed description.

#### 15 **BRIEF DESCRIPTION OF THE DRAWINGS**

Figure 1 is a perspective view of an exemplary tissue stabilizer of the present invention that uses a vacuum;

Figure 1a is an elevational view of a first step in a valve repair procedure using the tissue stabilizer of Figure 1;

20 Figure 1b is an elevational view of a second step in a valve repair procedure using the tissue stabilizer of Figure 1;

Figure 2 is a perspective view of a further tissue stabilizer of the present invention that also uses a vacuum;

Figure 2a is an elevational view of a step in a valve repair procedure using  
25 the tissue stabilizer of Figure 2;

Figures 3a-3c are perspective views of several embodiments of vacuum-based tissue stabilizers having tissue separating walls;

Figure 3d and 3e are sectional views of two different vacuum port configurations for the tissue stabilizers shown in Figures 3a-3c, the stabilizers  
30 shown in operation;

Figure 4a is an elevational view of a first step in a valve repair procedure using a mechanical tissue stabilizer with linearly displaceable tissue clamps;

Figure 4b is an elevational view of a second step in a valve repair procedure using the tissue stabilizer of Figure 4a;

Figure 4c is a detailed perspective view of a clamp of the tissue stabilizer of Figure 4a extended to grasp a valve leaflet from both sides;

5        Figure 5a is a perspective view of a suture-based tissue fastener of the present invention having toggles;

Figure 5b is a sectional view of the suture-based tissue fastener of Figure 5a loaded into a delivery needle;

10        Figure 6a-6c are elevational views of several steps in a valve repair procedure using a tissue stabilizer of the present invention and the suture-based tissue fastener shown in Figure 5a.

Figure 7a is a perspective view of an exemplary tissue stabilizing and fastening device of the present invention that uses a vacuum and needles to deliver suture-based fasteners having toggles through the tissue;

15        Figure 7b is an elevational view of a step in a valve repair procedure using the tissue stabilizing and fastening device of Figure 7a;

Figure 8 is an elevational view of an alternative tissue stabilizing and fastening device similar to that shown in Figure 7a;

20        Figure 9a is a perspective view of a further tissue stabilizing and fastening device of the present invention that uses a vacuum and needles to deliver suture-based fasteners having toggles through the tissue;

Figure 9b is a plan view of the distal tip of the device of Figure 9a;

Figures 10a-10c are several photographs of tissue being connected with suture-based fasteners having toggles;

25        Figures 11a-11c are elevational views of a tissue stabilizing and fastening device of the present invention having members deployable on a blind side of the tissue being connected;

30        Figures 12a-12e are elevational views of a tissue stabilizing and fastening device of the present invention having needles deployable on a blind side of the tissue being connected and a suture-based fastener;

Figure 13a is a perspective view of a further tissue stabilizing and fastening device of the present invention that uses a vacuum and deployable needles to deliver suture-based fasteners through the tissue;

Figure 13b is a plan view of the distal tip of the device of Figure 13a;

Figures 14a-14b are elevational view of a still further tissue stabilizing and fastening device of the present invention that uses vacuum and deployable needles to deliver suture-based fasteners through the tissue;

5        Figures 15a-15h are elevational and plan views of several steps in a valve repair procedure using the tissue stabilizing and fastening device of Figure 14;

Figures 16a-16c are sectional views of several steps in a tissue joining procedure using an exemplary tissue stabilizing and fastening device having needles for delivering a suture-based fastener;

10        Figure 16d is a detailed perspective view of a portion of the device seen in Figure 16b;

Figures 16e and 16f are isolated views of suture ties used with the suture-based fastener of Figure 16a;

15        Figures 17a-17c are elevational views of several steps in a valve repair procedure using an exemplary tissue stabilizing and fastening device for delivering a suture-based axial needle fastener;

Figure 18a is an elevational view of a first step in a valve repair procedure using an exemplary tissue fastening device of the present invention for delivering a spiral suture-based leaflet fastener;

20        Figure 18b is a detailed perspective view of a second step in a valve repair procedure using the spiral suture-based leaflet fastener of Figure 18a;

Figure 18c is an elevational view of a completed valve repair procedure utilizing the spiral suture-based leaflet fastener of Figure 18a;

25        Figure 18d is a detailed view of a pledget anchoring device used with the spiral suture-based leaflet fastener of Figure 18a;

Figures 19a-19d are elevational views of several steps in a valve repair procedure using an exemplary tissue stabilizing and fastening device of the present invention having vacuum stabilization and mechanical clamping;

30        Figure 20 is an elevational view of a mechanical tissue stabilizer with pivoting tissue clamps;

Figures 21a and 21b are elevational views of two steps in a valve repair procedure using the mechanical tissue stabilizer of Figure 21;

Figures 22a and 22b are elevational views of two steps in a valve repair

procedure using a mechanical tissue stabilizer of the present invention having preformed hooks;

Figure 22c is a detailed perspective view of a hook of the tissue stabilizer of Figure 22a extended to grasp a valve leaflet from the side opposite the tissue  
5 stabilizer;

Figures 23a and 23b are elevational views of two steps in a valve repair procedure using a mechanical tissue stabilizer of the present invention having spring-biased hooks;

Figure 23c is a detailed perspective view of two hooks of the tissue  
10 stabilizer of Figure 23a extended to grasp the valve leaflets from the side opposite the tissue stabilizer;

Figures 24a-24d are elevational views of several steps in a valve repair procedure using a mechanical tissue stabilizer of the present invention to deliver a non-suture-based fastener;

15 Figure 25a is a perspective view of an exemplary tissue staple useful with the methods and devices of the present invention and shown in an open configuration;

Figure 25b is a perspective view of the tissue staple of Figure 25a shown in a closed configuration;

20 Figures 26a-26c are elevational views of several steps in a valve repair procedure using an exemplary tissue fastening device of the present invention for delivering the tissue staple of Figure 25a;

Figure 27a is a perspective view of a further tissue stabilizing and fastening device of the present invention that uses a vacuum and delivers a staple to fasten  
25 tissue pieces;

Figure 27b is a sectional view of a step in a valve repair procedure using the tissue stabilizing and fastening device of Figure 27a;

Figure 27c is a perspective view of a completed valve repair procedure utilizing the tissue stabilizing and fastening device of Figure 27a;

30 Figure 28a is an elevational view of a further tissue fastening device of the present invention for delivering an alternative "toggle-like" tissue clip, the clip shown open;

Figure 28b is an elevational view of the tissue fastening device of Figure



28a, the clip shown closed;

Figure 29a is a detailed perspective view of a first step in a valve repair procedure using the tissue fastening device of Figure 28a;

Figures 29b and 29c are elevational views of two steps in a valve repair  
5 procedure using the tissue fastening device of Figure 28a;

Figure 30a is a perspective view of an alternative "toggle-like" tissue fastening clip, the clip shown open;

Figure 30b is a perspective view of the tissue fastening clip of Figure 30a shown closed;

10 Figures 31a-31d are elevational views of several steps in a valve repair procedure using an exemplary tissue fastening device of the present invention for delivering the tissue fastening clip of Figure 30a;

Figures 32a-32d are elevational views of various tissue fastening clips having barbed ends;

15 Figures 33a and 33b are sectional views of a two steps in a valve repair procedure using an exemplary tissue fastening device of the present invention for delivering a barbed tissue fastening clip of Figure 32a;

Figure 33c is an elevational view of a third step in a valve repair procedure using the tissue fastening device of Figure 33a;

20 Figure 34a-34f are elevational and perspective views of a tissue fastener of the present invention having spring-loaded jaws;

Figure 35a is a sectional view of a tissue fastening device for delivering the tissue fastener of Figure 34a;

25 Figures 35ba and 35c are sectional views of the tissue fastener of Figure 34a in both closed and opened positions around the tissue being connected;

Figure 36a-36c are elevational views of a further tissue fastener of the present invention having spring-loaded jaws; and

Figure 37a is a sectional view of a tissue fastening device for delivering the tissue fastener of Figure 36a;

30 Figure 37b is a sectional view of the tissue fastener of Figure 36a in a closed position around the tissue being connected;

Figure 38 is a perspective view of an exemplary integrated tissue stabilizer and fastening device of the present invention;

Figure 39 is a perspective view of the device of Figure 38 wherein the needle carrier is extended;

Figure 40 is a perspective view of the device of Figure 38 showing the initial release of the needles;

5        Figure 41 is a perspective view of the device of Figure 38 showing the needles captured within the vacuum ports;

Figure 42 is an exploded view of various components of the device of Figure 38;

10       Figure 43 is a perspective view of the device of Figure 38 wherein the needle carrier has been removed to clearly show the vacuum ports;

Figure 44 is a perspective view of an exemplary embodiment of a handpiece that is utilized with the device of Figure 38;

Figures 45a and 45b illustrate perspective views of alternate suture configurations used to practice the invention; and

15       Figure 46 is a perspective view of another exemplary embodiment of a handpiece that is utilized with the device of Figure 38.

## **DESCRIPTION OF THE PREFERRED EMBODIMENTS**

### **Exemplary Stabilizing Devices**

Figure 1 shows a tissue stabilizer 20 of the present invention that uses a vacuum to hold two tissue pieces. In this case, the tissue pieces are heart valve leaflets 22 and a valve repair procedure using the stabilizer 20 is depicted in Figures 1a and 1b. The tissue stabilizer 20 comprises a cylindrical probe 24 with at least one internal lumen (not shown) and having a flat distal end 26, a pair of vacuum ports 28 being disposed in the distal end 26. The ports 28 may be in communication with a common vacuum source, may be separately communicable with the source with internal valves (not shown), or may be in communication with different vacuum sources. The size of the ports 28 and magnitude of suction applied may vary depending on the application, but the ports 28 are desirably spaced apart a minimum distance to create two distinct suctions. In this manner, one leaflet or the other may be stabilized with one of the ports 28 without unduly influencing the other. In one example, the ports 28 have a minimum diameter of about 1/8 inch, and are spaced apart with a wall of at least 0.020 inches

therebetween.

The probe 24 desirably has a size suitable for minimally invasive surgery. In one embodiment probe 24 is part of a catheter based percutaneous delivery system. In that case probe 24 is a catheter tube having a lumen or lumens  
5 connecting vacuum ports 28 to the vacuum source or sources. The catheter would be long enough and have sufficient steerability and maneuverability to reach the heart valve from a peripheral insertion site, such as the femoral or brachial artery. One particular advantage of the present invention is the ability to perform valve repair surgery on a beating heart. The procedure shown in Figures 1a and 1b is a  
10 mitral valve repair with an approach of the probe 24 from the left atrium 30. The atrium 30 has lower pressures than the ventricle 31, and thus there is less blood leakage and less turbulence imparted to the probe 24. First, the anatomical structures, including the location of the leaflets 22, can be visualized using echo technology, or other means. One leaflet 22 may be stabilized with one of the ports  
15 28, and that leaflet 22 then manipulated toward the other leaflet 22, which is then also stabilized. Again, any of the fasteners disclosed herein may then be used to secure the leaflets 22 together.

Figure 2 illustrates another tissue stabilizer 32 similar to that shown in Figure 1 and that also uses a vacuum. The tissue stabilizer 32 includes a probe  
20 body 34 having at least one internal lumen (not shown) and an angled or tapered nose 36 on a distal end. A vacuum port 38 is provided on each face of the tapered nose 36. Figure 2a shows a valve repair procedure using the tissue stabilizer 32 of Figure 2, wherein a distal tip 40 of the nose 36 is exposed to the ventricular 31 side of the leaflets 22. Because of this exposure, various leaflet fastening devices can  
25 be delivered through the probe 34 to the ventricular side of the leaflets 22, as will be seen below.

Figures 3a-3c show three vacuum-based tissue stabilizers having tissue separating walls. In Figure 3a, a tissue stabilizer 40 includes a flat distal face 42 having a pair of distally-directed tissue separating walls 44 extending therefrom,  
30 and defining a gap 46 therebetween. The stabilizer 40 contains one or more lumens in communication with vacuum ports 48 that open on both sides of the walls 44. There are four such ports 48 shown, one on each side of each wall 44. In addition, a fastener channel 50 opens at the distal face 42 between the walls 44,

and facing the gap 46 therebetween. The fastener channel 50 can be used to deliver tissue fasteners, as described below.

In Figure 3b, a tissue stabilizer 52 includes a flat distal face 54 having a single distally-directed tissue separating wall 56 extending therefrom. The stabilizer 52 contains one or more lumens in communication with circular vacuum ports 58 that open on both sides of the wall 56. There are two such ports 58 shown, one on each side of each wall 56.

In Figure 3c, a tissue stabilizer 60 includes a flat distal face 62 having a single distally-directed tissue separating wall 64 extending therefrom. The stabilizer 60 contains one or more lumens in communication with semi-circular vacuum ports 66 that open on both sides of the wall 64. There are two such ports 66 shown, one on each side of each wall 64.

Figure 3d and 3e show two different vacuum port configurations for the tissue stabilizers 40, 52, or 60 shown in Figures 3a-3c. As mentioned above, the stabilizers 40, 52, or 60 may have one or more lumens in communication with one or more ports. In Figure 3d, two lumens 68a and 68b provide separate suction control to the associated ports. Thus, one tissue piece 70a is seen stabilized by the right-hand vacuum port, while the left-hand port is not operated. Alternatively, a single lumen 72 in communication with two vacuum ports is seen in Figure 3e, and both tissue pieces 70a, 70b are stabilized simultaneously. In both these views, the tissue separating wall 74 is shown between the tissue pieces to be joined.

Fastening devices can thus be delivered via the wall 74, or through a gap formed for that purpose, such as the gap 46 and fastener channel 50 seen in Figure 3a.

Figures 4a-4c show a mechanical tissue stabilizer 80 with a four-part, linearly displaceable tissue clamp 82. On each side, a lower clamp 84 is separated from an upper clamp 86 and inserted between two tissue pieces (in this case valve leaflets 22). As the lower and upper clamps 84, 86 are brought together, as seen in Figure 4b, they physically clamp and stabilize the leaflet 22. Small teeth 88 on the clamps 84, 86 may be provided for traction. The clamps 84 and 86 on each side are individually actuated to enable grasping of one leaflet 22 at a time.

#### **Exemplary Suture-Based Tissue Fasteners**

Figure 5a illustrates a suture-based tissue fastener 90 of the present

invention including toggles 92 secured to the end of suture threads 94. Figure 5b is a sectional view through a needle 96 used to deliver the tissue fastener 90.

Specifically, the toggle 92 and suture thread 94 is seen loaded into the lumen of the needle 96, and a pusher 98 is provided to urge the tissue fastener 90 from the distal end thereof.

Figure 6a-6c depict several steps in a valve repair procedure using the tissue fasteners 90 shown in Figure 5a. A probe, such as the probe 20 seen in Figure 1 having vacuum ports for tissue stabilization, provides lumens for two of the needles 96 of Figure 5b. The lumens with the vacuum parts 96 may receive the needles 96 or additional lumens may be provided. The sharp ends of the needles 96 pierce the leaflets, and the pushers 98 are displaced (separately or in conjunction) to deploy the tissue fasteners 90. After the needles 96 are retracted, the toggles 92 anchor the tissue fasteners 90 on the ventricular 31 side of the leaflets 22. The suture threads 94 are then tied off on the atrial 30 side to secure the leaflets 22 together, as seen in Figure 6c.

Figure 7a is a perspective view of an exemplary tissue stabilizing and fastening device 100 that uses the principles of vacuum stabilization and a suture-based toggle fastener, as seen in Figures 5a and 5b. The device 100 includes a probe 102 defining several lumens (not shown) therein that open on a distal face. Two lumens 104 open at a proximal end and receive two of the needles 96 for delivering the fasteners. Two other lumens communicate through two side arms 106 with sources of vacuum. Figure 7b shows the device 100 in use in a valve repair procedure, with the two needles 96 having pierced the leaflets 22 and delivered the fasteners 90. The leaflets 22 are held to the probe 102 using the vacuum ports.

Figure 8 illustrates an alternative tissue stabilizing and fastening device 108 similar to the device 100 of Figure 7a, but having a pointed nose with two concave faces 110 in which the vacuum ports are located. The device 108 functions as described above, with a fastener deliver needle shown in phantom having pierced the left leaflet 22.

Figures 9a and 9b show a still further tissue stabilizing and fastening device 112 that uses a vacuum and needles to deliver suture-based fasteners having toggles through the tissue. The device 112 is quite similar in function to the device

102 of Figure 7a, but has a modified distal end, as best seen in the plan view of Figure 9b. Specifically, a central tissue separating wall 114 is provided with a pair of vacuum ports 116a on one side, and another pair 116b on the other. Again, the port 116 may be separately or commonly supplied with vacuum. Fastener delivery  
5 lumens 118a and 118b are located on each side of the wall. The aforementioned needles 96 or other such device may be delivered through the lumens 118 to pierce and fasten the tissue pieces.

Figures 10a-10c are several photographs of tissue being connected with suture-based fasteners having toggles. Figure 10a illustrates the toggle 92 being  
10 deployed. Figure 10b illustrates the needles 96 being retracted, and Figure 10c illustrates the sutures 94 being tied.

Figures 11a-11c show a tissue stabilizing and/or fastening device 120 having members deployable on a blind side of the tissue being connected. In this context, "blind side" means the side of the tissue pieces opposite the side to which  
15 the device has direct access. The deployable members may be clamps to stabilize the tissue pieces, or fastening devices that contact the tissue pieces on the blind side.

The device 120 includes a probe 122 with lumens, and a distal tip 123 that is narrower than the probe 122 and defines concave transition faces 124. A  
20 vacuum port 126 may be provided in each transition face 124 for tissue stabilization, or a clamping mechanism may be stowed in a space 128 in the distal tip 123. Figure 11c shows the clamp 129 (or fastener) in a deployed state.

Figures 12a-12e illustrate a tissue stabilizing and fastening device 130 having needles 132 deployable on a blind side of the tissue being connected. The  
25 device 130 may be configured like the device 120 of Figure 11a, with the space 128 receiving needles 132. A common suture thread 134 connects the needles 132 and is used to secure the tissue pieces 70 together. Thus, as seen in the sequence of Figures 12a-12e, the needles 132 are first advanced to the blind side of the tissue pieces 70 and deployed outboard of the distal tip. The entire device 130 is  
30 retracted, as in Figure 12c, to cause the needles 132 to pierce the tissue pieces 70. The two needles 132 are then disengaged from the device 130, and each other, as in Figure 12d, and the entire device 130 once again retracted to pull the needles 132 out from the pieces 70, leaving the connected suture joining the two pieces 70

(Figure 12e). The suture 132 can then be tied off, or otherwise secured on the upper side of the tissue pieces 70.

Figure 13a is a more detailed view of a tissue stabilizing and fastening device 140 similar to that shown in Figures 12a-12e. The device 140 features two  
5 semi-circular vacuum ports 142 that stabilize the tissue pieces being joined. The distal tip includes a centered and distally-directed frame 144 defining a space 146 therein. The needles 148 are connected to the frame 144 and reside within the space 146. Although not shown, a deployment mechanism is also provided that causes the needles to pivot outward about their distal ends, and also disengages the  
10 needles 148 from the frame 144.

Figures 14a-14b illustrate a tissue stabilizing and fastening device 150 having needles 152 deployable on a blind side of the tissue being connected. The device 150 includes a probe 154 having two vacuum ports 156a, 156b for stabilizing the tissue pieces 70 being joined. A distal tip includes an extension  
15 member 158 having a centered and distally-directed frame 160 defining a space 162 therein. The extension member 158 may be configured relatively narrow in one direction such that it can enter the ventricle 31 between the leaflets 22 with minimum risk to the chordae (not shown). The frame 160 may be extended and retracted within the probe 154. The needles 152 are connected to the frame 160  
20 and reside within the space 162. A deployment mechanism (not shown) is provided that causes the needles 152 to pivot outward about their distal end, and also disengages the needles 152 from the frame 160. A common suture thread 166, which is stored within the probe 154, connects the needles 152 and is used to secure the tissue pieces 70 together. In the embodiment shown in Figure 14, the  
25 device 150 includes two needles 152 and a single suture 166. Other embodiments may include four needles with separate sutures. Additional needles may be provided if needed.

Figures 15a-15h illustrate several steps in a tissue joining procedure using the tissue stabilizing and fastening device 150. Referring to Figure 15a, the probe  
30 154 is passed through the atrium 30 via an access cannula or catheter 164. During this stage, the frame 160 is in its retracted position. The probe 154 is secured to the atrium 30 with a purse string 166 or any other manner known to one skilled in the art. Figures 15b-15d illustrate stabilization of the leaflets 22 being joined.

Suction is provided to the first vacuum port 156a, and the probe 154 is manipulated to capture the first leaflet 22. With the first leaflet 22 captured, suction is provided to the second vacuum port 156b, and the second leaflet 22 is captured. Referring to Figure 15e, the frame 160 is advanced into the ventricle 31 by extending the frame 160, and the needles 152 pivot outward about their distal end. The frame 160 is returned to its retracted position, and the needles 152 pierce the leaflets 22 and are directed into needle receivers 168, as shown in Figure 15f. As shown in Figure 15g, suction to the vacuum ports 156a, 156b is terminated, and the leaflets 22 are released. The needle receivers 168 pull the needles 152 through the leaflets 22, and the suture 166 "pays-out" behind the needles 152. The suture 166 trails out as the probe 154, with the needles 152 stored within the probe 154, is withdrawn from the access cannula or catheter 144 (see Figure 15g). The two needles 152 are then disengaged from the probe 154, and the suture 166 can then be tied off, or otherwise secured on the upper side of the leaflets 22.

Figures 16a-16c are sectional views of several steps in a tissue joining procedure using a tissue stabilizing device 170 having a fastening device 172 with two needles 174 for delivering a suture-based fastener. The stabilizing device 170 includes a distal tip with oppositely-facing concave surfaces 176 for contacting and stabilizing the tissue pieces 70 (with, e.g., vacuum ports). Although not shown, the fastening device 172 is stowed in a channel within the stabilizing device 170 and may be linearly deployed through apertures formed in the concave surfaces 176.

The device 170 further includes a sliding plate 178 with two throughholes 180 in the distal end, as seen in Figure 16d. The fastening device 172 has a spring bias that causes the needles 174 to curve inward when permitted. Therefore, as seen in Figure 16b, the fastening device 172 has been freed from the channels past the concave surfaces 176 and the needles 174 have curved inward to be received in the plate holes throughholes 180. The needles 174 first pass twice through each respective tissue piece 70. The plate 178 is then retracted upward into the device 170, thus pulling the needles 174 through the tissue pieces 70. The fastening device 172 is desirably made of a highly pliable material, such as a superelastic like Nitinol, so that it can be pulled through sharp angles. Suture threads 182 are connected to each needle 174 and are also pulled through the tissue pieces 70. Figure 16c shows the result, with the suture thread 182 passed through both tissue



pieces 70. Figures 16e and 16f illustrate two suture ties to complete the procedure.

Figures 17a-17c illustrate several steps in a valve repair procedure using a tissue stabilizing and fastening device 190 for delivering a suture-based axial needle fastener 192. The device 190 includes a clamping mechanism 194, much  
5 like the clamping device 82 seen in Figures 4a-4c. The two sides are independently controllable, so as to grasp and pierce one leaflet 22 and then the other. The fastener 192 includes a pair of needles 196 initially mounted in the lower portion of the clamping mechanism 194 and facing upward. The two needles 196 are connected with a suture thread 198. When the clamping  
10 mechanism 194 actuates, the needles 198 pierce the respective leaflet 22. The upper portion of each side then pulls the needle 196 completely through the leaflet 22, and the lower portion is retracted from the blind side of the leaflets 22. The resulting suture loop is tied off, as seen in Figure 17c.

Figures 18a-18d illustrate a valve repair procedure using a tissue fastening  
15 device 200 and a spiral suture-based leaflet fastener 202. The leaflets 22 are stabilized, using one of the means disclosed herein (such as suction from two angled faces 204), and the fastener 202 is deployed. The fastener 202 comprises a helical needle 206, a trailing suture thread 208, and a pair of pledget anchoring devices 210. Figure 18d is a detailed view of the pledget 210 used with the spiral  
20 suture-based leaflet fastener 202.

Figures 19a-19d illustrate a tissue stabilizing and fastening device 220 that uses the principles of vacuum stabilization/mechanical clamping and a suture-based toggle fastener. The device 220 includes a probe 222 having two vacuum ports for initial tissue stabilization. In addition to the vacuum ports 224, the device  
25 220 includes a mechanical tissue stabilizer 226 with a four-part, rotatable and linearly extendable capture hooks 228. The distal tip includes a centered and distally-directed frame 230 defining a space 232 therein. The capture hooks 228 are folded flat within the space 232 and are rotatably and slidingly coupled to the probe 222 so that the capture hooks 228 may be rotated about 90 degrees and  
30 retracted to a capture position, wherein the leaflets 22 are "pinched" between distal ends of the capture hooks 228 and shoulders 234 of the probe 222. The two vacuum ports 224 also provide lumens for two of the needles 96 of Figure 5b. The sharp ends of the needles 96 pierce the leaflets 22, and the pushers 98 are displaced

(separately or in conjunction) to deploy the tissue fastener 90. After the needles 96 are retracted, the toggles 92 anchor the tissue fasteners 90 on the ventricular 31 side of the leaflets. The suture threads 94 are then tied off on the atrial 30 side to secure the leaflets 22 together, as seen in Figure 6c.

5        Figures 19a-19d illustrate several steps in a valve repair procedure using the tissue stabilizing and fastening device 220. The stabilizing and/or fastening elements of the device 220 is formed relatively narrow in one dimension to enable it to be slipped between the two leaflets 22, wherein the capture hooks 228 are stored in a folded and extended position. The two leaflets 22 are initially stabilized  
10 by the vacuum ports 224. To further stabilize the leaflets 22, the capture hooks 228 are rotated 90 degrees and retracted, wherein the leaflets 22 are physically clamped against the shoulders 234 of the probe 222 and the distal ends of the capture hooks 228. It is noted that both vacuum stabilization and mechanical clamping do not have to be implemented to stabilize the leaflets 22. In certain  
15 applications, implementing only one of the mechanisms may be desirable. With the leaflets 22 properly stabilized, the needles 96 are driven forward to pierce the leaflets 22. The capture hooks 228 reduce the likelihood of losing grasp of the leaflets 22 during the piercing process. As shown in Fig. 5b, the pushers 98 are displaced (separately or in conjunction) to deploy the tissue fastener 90. After the  
20 needles 96 are retracted, the toggles 92 anchor the tissue fasteners 90 on the ventricular 31 side of the leaflets 22. The suture threads 94 are then tied off on the atrial 30 side to secure the leaflets 22 together, as shown in Figure 6c.

#### **Exemplary Mechanical Stabilizers and Fasteners**

Figure 20 shows a mechanical tissue stabilizer 240 that can be used to grasp  
25 tissue pieces 70 to be joined. The stabilizer 240 includes a probe 242 having a pair of pivoting arms 244 on a distal end. The arms 244 each have teeth 246 for added purchase on the tissue. Figures 21a and 21b illustrate a valve repair procedure initiated in accordance with the present invention using the tissue stabilizer 240.

Figures 22a and 22b illustrate steps in a valve repair procedure using a  
30 mechanical tissue stabilizer 250 having preformed hooks 252. The hooks 252 are curled into approximately a three-quarter circle and deployed on the blind side of the leaflets 22 to grasp and stabilize them. The linear displacement of each hook

252 is separately controllable.

Figures 23a-23c illustrate steps in a valve repair procedure using a mechanical tissue stabilizer 260 having spring-biased hooks 262. The hooks 262 curl into approximately a three-quarter circle when deployed, and are advanced on the blind side of the leaflets 22 to grasp and stabilize them. Again, the linear displacement of each hook 252 is separately controllable.

Figures 24a-24d illustrate a valve repair procedure using a mechanical tissue stabilizer 270 similar to both the stabilizers shown in Figures 22 and 23. After hooks 272 have stabilized the leaflets 22, a retainer 274 is slid down link rods 276 of each hook 272 (Figure 24c). Figure 24d shows the retainer 274 having reached the curvature of the hooks 272, at which point the link rods 276 are severed using conventional means. For example, the link rods 276 may be made of a polymer material, and a cutter deployed adjacent the device 270 to sever them. Again, the link rods 276 are separately displaceable as seen in Figure 24b.

#### 15 Exemplary Staple and Clip-Type Fasteners

Figure 25a shows an exemplary tissue staple 280 for joining two tissue pieces in an open configuration. The staple 280 includes a bridge portion 282 and four gripping arms 244, two on each side. The gripping arms 284 are initially curled in a semi-circle upward from the plane of the bridge portion 282 and terminate in sharp points approximately in the plane of the bridge portion 282. Figure 25b shows the staple 280 when closed, with the gripping arms 284 curled underneath the plane of the bridge portion 282 toward each other.

Figures 26a-26c illustrate several steps in a valve repair procedure using an exemplary tissue fastening device 290 for delivering the tissue staple 280. The device 290 includes a probe 292 with an internal lumen 294 within which a pusher 296 is slidable. A stop member 298 is also provided underneath the bridge portion 282 of the staple 280 to prevent displacement of the bridge portion 282 toward the leaflets 22. After stabilizing the leaflets 22, the pusher 296 displaces downward which causes the staple 280 to undergo a plastic deformation from the configuration of Figure 25a to that of Figure 25b. The sharp points of the gripping arms 284 pass through the leaflets 22 and anchor the staple 280 therein. Finally, the stop member 298 is disengaged from under the bridge portion 282, and the

device 290 is retracted.

Figure 27a illustrate the use of a tissue stabilizing and fastening device 300 for deploying the staple 280 of Figure 25. The device 300 is quite similar to the device 290 of Figure 26, with an exemplary stabilizing means shown in the form of  
5 vacuum chamber(s) 302 on each side of the staple deployment mechanism.

Figures 28a and 28b illustrate a further tissue fastening device 310 of the present invention for delivering an alternative "toggle-like" tissue clip 312. In Figure 28a the clip 312 is shown open, while in Figure 28b the clip 312 is shown closed. The clip 312 is plastically deformed from open to close using a clamping  
10 mechanism 314 that flattens a ring-shaped head portion 316 of the clip 312. Two pincher arms 318 thus pivot toward each other and grasp and hold tissue therebetween.

Figures 29a-29c depict steps in a valve repair procedure using the tissue fastening device 310 of Figure 28. One method for inserting the device 310, as well as many other devices of the present invention, between the two leaflets 22 is  
15 detailed in Figure 29a. Specifically, the stabilizing and/or fastening elements of the devices of the present invention can be formed relatively narrow in one dimension to enable them to be slipped between two tissue pieces so that the pieces can then be fastened together from the blind side. Thus, for example, the tissue  
20 fastening device 310 is seen in Figure 29a rotated to orient the narrow dimension in line with the gap between the leaflets 22.

Figures 30a-30b and 31a-31d illustrate an alternative tissue fastening device 320 for delivering another "toggle-like" tissue fastening clip 322. In contrast to the clip 312 of Figure 28, the clip 322 pierces the tissue pieces 70 from  
25 the front side, and is then deformed to clamp the tissue pieces 70 together.

Figures 32a-32d illustrate various embodiments of barbed clips 330, 332, 334, 336 used to fasten tissue pieces together using the principles of the present invention. The barbed clips include a bridge portion 338, 340, 342, 344 and terminate in sharp points.

30 Figures 33a-33c illustrate several steps in a valve repair procedure using an exemplary barbed clip deployment device 350 for delivering the barbed clip 330. The device 350 includes a probe 352 with an internal lumen 354 within which an internal driver 356 is slidable. A stop member 358 is provided at the

distal end of the probe 352 to spread the two barbs away from each other as it is pushed forward. The tips of the barbed clip 330 are displaced towards the leaflets 22 by downwardly sliding the driver 356. After the clip 330 pierces the leaflets 22 from the front side, the clip 330 is disengaged from the device 350 as shown in  
5 Figure 33c. When the clip 330 is disengaged from the device 350, it returns to its retracted position and compresses the leaflets 22 together. Again, any of the stabilizers of the present invention can be used in conjunction with the deployment device 350.

Figures 34a-34f illustrate a spring-loaded clip 360 used to fasten tissue  
10 pieces 70 together. The clip 360 comprises a spring portion 362 and two arms 364, and the arms 364 include a plurality of barbs 366. The distal ends of the arms 364 are tapered to enable the clip 350 to pierce the leaflets 22, and the arms 364 are configured to overlap each other after closure (see Figure 34c). Figures 35a-35c illustrate a valve repair procedure using a clip deployment device 370 for  
15 delivering the spring-loaded clip 360. The device 370 includes a probe 372 with an internal lumen 374, and a pusher 376 is slidably coupled to the internal lumen 374. A sleeve 378 is disposed between the pusher 376 and the internal wall of the lumen 374. The spring portion 362 of the clip 360 is housed within the sleeve 378 in its open position, wherein the spring portion 362 is compressed by the sleeve  
20 378. As seen in the sequence of Figures 35a-35c, downward movement of the pusher 376 causes the clip 360 to move downward and pierce the leaflets 22 from the front side. The clip 360 is pushed downward at a velocity adequate to insure penetration without dislodging the leaflets 22 from the vacuum source. As the clip 360 is disengaged from the device 370, the clip 360 automatically springs to its  
25 closed position and compresses the leaflets together.

Figures 36a-36c illustrate another embodiment of a spring-loaded clip 380 used to fasten tissue pieces together. The clip 380 comprises a spring portion 382 and two arms 384 having distal ends which are tapered and extend inwardly to pierce and lockingly secure the leaflets 22. A gap 386 exists between midportions  
30 of the arms 384 when the clip 380 is in its closed position.

Figures 37a and 37b illustrate a clip deployment device 390 having a probe 392 with an internal lumen 394 and a pusher 396 slidably coupled to the internal lumen 394. The spring portion 382 is retained in a compressed state

within a housing member 398 such that the clip 380 is held in an open position. Downward movement of the pusher 396 causes the clip 380 to move downward and pierce the leaflets 22 from the front side. As the spring portion 384 exits the housing member 398, the clip 380 automatically springs into its closed position  
5 and lockingly secures and compresses the leaflets 22.

#### **Exemplary Integrated Stabilizing and Fastening Device**

Figures 38-46 illustrate another exemplary embodiment of an integrated tissue stabilizing and fastening device 400 which captures tissue pieces, such as valve leaflets, with vacuum and fastens the tissue pieces with sutures. The device  
10 400 is similar to the devices illustrated in Figures 11-15 in that it comprises a slender distal portion which accesses the heart valve trans-atrially. The device 400 is placed through a specialized cannula and it has a proximal handpiece portion which provides user controls. In an exemplary embodiment the distal portion is approximately 10 mm in diameter and it terminates in vacuum ports and a needle  
15 array as depicted in Figures 38 through 41. The handpiece portion contains individual vacuum port controls and needle deployment controls as generally depicted in Figure 44. The device 400 is connected to a vacuum source via a flexible hose. The illustrated device 400 is utilized to grasp the tissue pieces and place the sutures correctly. Remote tying and cutting of the sutures can be  
20 accomplished with a separate device. The following description of the use of the device 400 will be made with respect to the stabilizing and fastening of the leaflets of a mitral valve. However, those of skill in the art will appreciate that the device can also be used to stabilize and fasten other physiological tissues. A more detailed description of the device 400 follows.

25 Figures 38-41 illustrate device 400 in various modes of operation. Device 400 comprises vacuum ports 402 and 404 at the distal tip of device 400 which are connected to the vacuum source 418 (shown in Figure 44). Needle carrier 406 is centrally disposed at the distal end of device 400 and is configured to be extended from and retracted back into device 400. Needles 408 are mounted on mounting  
30 blocks 410 within carrier 406 and mounting blocks 410 are pivotably attached to carrier 406 via pivot pin 412. Needle catchers 414 are retained in ports 402 and 404 to grip and retain needles 408 when needle carrier is retracted back into device

400 upon completion of the procedure.

Figure 44 illustrates an exemplary handpiece 416 which connects vacuum source 418 to device 400 and delivers vacuum to vacuum ports 402, 404 at the distal tip of the device. Pinch valves 420 mounted on the handpiece 416 of the device normally constrict the vacuum lines. By individually manipulating each valve, the operator can differentially control access to the vacuum source. By partially deflecting one valve, the operator permits momentary access by one of the vacuum ports to the vacuum source. By fully deflecting one of the valves, the operator permits continuous access to the vacuum source. The provision of separate, individually controlled valves permits the delivery of differential vacuum to one or the other of ports 402 and 404. This may be very helpful in certain cases of valve prolapse where it is necessary to capture one leaflet and move it laterally with respect to the second leaflet to facilitate final capture.

The vacuum system has, of necessity, two different operating modes. Initially, it is necessary to capture the leaflets. This requires relatively high flow rates to attract a leaflet to a vacuum port. In an exemplary embodiment the flow rate is approximately 10 cc per second. Since this flow rate is capable of exsanguinating and destabilizing the beating heart, the invention provides for quick and efficient leaflet capture. Efficient capture requires that the vacuum port be close to the leaflet when the vacuum is turned on. Proper placement of device 400 with respect to the leaflets is facilitated by placement of echogenic members at or near vacuum ports 402 and 404 to enhance visualization by echo.

Echogenicity is enhanced by the proper choice of materials. The device, being entirely of plastic except for small metal parts in the immediate vicinity of the ports, takes advantage of the relatively high visibility of metal while avoiding the shadowing properties of large masses of metal. The metal parts in question are needle catchers 414, needles 408 and pivot pin 412. Since these parts are located near the vacuum ports 402 and 404 in the long axis of the device, they serve to locate ports 402 and 404 axially relative to the valve leaflets prior to vacuum application. Since they are discontinuous and symmetrical about ports 402 and 404 in the short axes, they facilitate the correct radial orientation of the ports relative to the valve leaflets. Echogenicity is further enhanced by a polymer coating which can be wholly or selectively applied to the ports 402 and 404. This

coating creates a microscopic boundary layer which effectively separates the ports from the blood under echo visualization.

In an exemplary embodiment, the vacuum surfaces of the ports 402 and 404 are angled between zero and ninety degrees relative to a plane normal to the long axis of the device. This is intended to conform somewhat to the shape of the valve leaflets. In another exemplary embodiment the ports are angled between 15 to 40 degrees relative to a plane normal to the long axis of the device. In yet another embodiment the ports are angled at about 25 degrees relative to that plane.

Once the leaflets have been captured, the second operating mode of the vacuum system is to hold the leaflets in position for suture application without additional exsanguination. This implies high holding force and no flow. These properties are primarily a function of pressure differential, port area and port shape. In one embodiment, adequate holding force is obtained at a maximum differential pressure with port areas in the approximate range of 0.03-0.04 square inch per port. In the embodiment illustrated in Figure 43, a geometrically optimized cylindrical device is shown having two separate "D" shaped ports 402 and 404. The illustrated device 400 has about 10 mm in diameter. Since a vacuum port with the highest ratio of area to perimeter (i.e., a circle) will have the highest average peel away strength, some modification of the "D" shaped port is useful for functional optimization. This is accomplished in the device by filling in the corners of the "D" where the arc meets the straight portion at acute angles. This can be seen clearly on port 402 in Figure 38. The corners which have been eliminated represent the part of the "D" shape least resistant to peel away of the leaflet which is being held by vacuum.

Vacuum ports 402 and 404 further have barriers 422 which serve two distinct purposes. Barriers 422 support the valve leaflet to prevent it from being sucked deep into the ports 402 and 404, thereby minimizing tissue trauma. This has the further useful effect of controlling the position of the leaflet relative to the suture needles so that the latter penetrate the leaflet in a predictable way, placing sutures the correct distance from the edge of the leaflet for reliable repair. In the illustrated embodiment of Figure 43, the barriers are recessed below the perimeter of the "D" slot. In an exemplary embodiment the barriers are recessed about 0.02 inches. This slightly distorts the valve tissue and creates resistance to displacement



of tissue as it is moved laterally by the device to approximate the leaflets. If the barriers were not recessed, the only resistance to lateral drag would be the coefficient of friction between the port surface and the leaflet which is likely to be low in the bloody environment.

5           A pre-evacuated sterile bottle 418 serves as a passive vacuum source for capturing and holding the leaflets. In an exemplary embodiment, the system is designed to minimize total exsanguination to about 200 cc per procedure. A standard 2 liter bottle can provide that amount of flow with negligible increase in absolute pressure. This offers a significant advantage over utility vacuum sources  
10 in hospital operating rooms and dedicated active pumps. Utility sources are not well controlled and active pumps present cost, convenience and sterility issues.

Once captured, leaflets will be fastened by remotely applied sutures. The mechanism by which this is accomplished is shown in Figures 39 through 42 as will be discussed below. Figures 45a and 45b illustrates two exemplary suture  
15 configurations which the system can provide, depending on the way in which the sutures and needles are loaded into the device.

In one embodiment, two lengths of suture (not shown) are used with a straight needle 408 attached to each suture end. Sutures are inserted into a coaxial hole in the end of the needle opposite the point and the body of the needle is  
20 crimped to retain the suture using conventional suture technology. A groove near the tip of the needle provides a means for grasping and pulling the needle through after it has pierced the valve leaflet. Sutures can be monofilament or braided or other types suitable for cardiovascular use. In an exemplary embodiment, a size 4-0 monofilament suture capable of gamma sterilization (e.g. Novafil) is used since  
25 the internal configuration of the device favors radiation sterilization and it is desirable to be able to sterilize the entire system at one time. The needles will receive a lubricious coating (e.g. silicone) to reduce penetration force and friction.

In one embodiment, the needles and sutures are an integral part of a single use completely disposable device. In a second embodiment, the needles, sutures  
30 and associated hardware may be packaged as a cartridge which plugs into a reusable device. This device can be limited to multiple use in a single procedure, or reusable for multiple procedures.

Needle carrier 406 further comprises needle driver assembly 424. Driver

assembly 424 includes blocks 410, axle 412, needle driver 426, and cams 428.

Needles 408 are slidably mounted in blocks 410 which pivot about axle 412.

Blocks 410 may be slotted in the area of the hole which receives the needle so that the needles can be held in place by controlled friction. Sutures (not shown)

5 protruding from the ends of the needles can be routed along the sides of the needle carrier 406 in grooves provided for that purpose. The needles are initially recessed into the body of the device 400 by virtue of the recessed position of carrier 406, as shown in Figure 38. The position of the needles in this state is shown in Figure 39. The needle mounting blocks 410 are pivoted so that needles 408 lie in a single row  
10 within the confines of the needle carrier 406. One end of driver element 426 which drives the needle carrier 406 in and out of the distal device tip is positioned just above the needle points so that the needles 408 are retained in their holders 410 against any drag which might tend to dislodge them. The other end of the driver element 426 is connected to a control at the proximal end of the device by which  
15 the operator manipulates the needles 408.

After the valve leaflets are captured as described above, needle carrier 406 is advanced from the position shown in Figure 38 to that of Figure 39. The needle mechanism at this stage is compactly configured to avoid entangling chordae tendineae or papillary muscles during capture of the leaflets and initial needle  
20 deployment. Cams 428 are then advanced, pivoting the needle mounting blocks 410 and causing the needles 408 to deploy as shown in Figure 40. Protruding stops on blocks 410 limit the angular deployment of the needles to the proper position for penetrating the valve leaflets. These stops come to rest against the needle carrier 406. The individual parts can be seen clearly in Figure 42.

25 With the needles deployed, the needle carrier 406 is retracted proximally, causing the needle points to penetrate valve leaflets (not shown) and enter the vacuum ports 402 and 404. As the needles continue to move proximally, the points enter the needle catchers 414 which are essentially one way gripping devices. The needles advance until their grooves engage the jaws of the needle  
30 catchers 414. Needle catchers 414 are retained in the ports 402 and 404 by a vacuum adapter 430, shown in Figure 42.

The needle carrier 406 advances distally pulling the needle mounting blocks 410 away from the needles which are retained by the needle catchers 414.

The vacuum is disconnected and the device is withdrawn from the heart along with the needles 408 which are firmly held by the catchers 414. As the needles move outward, the sutures, which are loosely deployed in the body of the device 400, are pulled through the leaflets 432 and 434 to one of the positions shown in Figures 5 45a and 45b. Once the device is free of the access cannula, sutures 436 and 438, or 440 and 442, are cut from the needles and tied remotely using a knot rundown tool with an integral cutter to remove excess suture material.

The proximal control handpieces 416 shown in Figures 44 and 46 are illustrative of alternate approaches to controlling the system. One objective is to 10 permit single handed control of the vacuum ports and suture needles without destabilizing the device. It is useful to locate and hold the device precisely in relation to the beating heart in order to accomplish the surgical procedure with minimal blood loss. In operation, the surgeon will use one hand to stabilize the distal end of the device via the cannula where it enters the atrium and the other 15 hand to operate the vacuum and suturing controls. Control functions are described below.

In the device shown in Figure 44, handpiece 416 has a pistol-like configuration which includes a shaft portion 446 and a handle portion 448. A pair of vacuum controls 420 are positioned akin to pistol hammers at the back of shaft 20 portion 446 and at the top of handle portion 448. In this embodiment vacuum controls 420 are thumb operated. Vacuum controls 420 are separately capable of being partially activated or fully activated by a toggle mechanism (not shown). When partially activated, the associated vacuum line is momentarily opened, allowing blood to flow into the vacuum source 418. If one of the controls 420 is 25 released it will return to its normally closed position and flow to the associated line will stop immediately. Once a leaflet has been captured the control 420 can be moved to its extreme position where it will remain due to an internal toggle action. In this case vacuum is applied to retain the leaflet which, in turn, blocks the port, preventing blood flow.

30 In another embodiment shown in Figure 46, the pair of vacuum controls 420 are located in the body 416 below the shaft portion 446 and in front of the handle portion 448. In this embodiment the vacuum controls 420 function like a pistol trigger, just above the needle control trigger 444, so that they can be

operated individually by the index finger. In the arrangement shown, it will be necessary to actuate the control nearest the index finger first. The first action momentarily opens the vacuum line as described above. When the leaflet is captured the control is depressed further, causing it to latch into place by an  
5 internal toggle action. The second control 420 is now accessible to the index finger for capture of the second leaflet in similar manner.

In the embodiments shown in Figures 44 and 46 the trigger 444 is pivotably mounted in body 416 to control needle deployment after the leaflets are captured. The trigger is connected to needle driver 426 by a linkage internal to the body 416  
10 which establishes the correct direction and stroke. The device is supplied with the trigger fully depressed to hold the needle array in the position shown in Figure 38 relative to the vacuum ports 402 and 404. An internal latch in 416 retains the trigger. Once the leaflets have been captured the trigger is released, allowing the needles to advance to the position shown in Figure 39. Near the end of the trigger  
15 stroke, needle driver 426 bears on cams 428 which, in turn, bear on blocks 410 causing the needles to deploy outward as in Figure 40.

Squeezing the trigger 444 moves the needles proximally through the valve leaflets and into the vacuum ports 402 and 404 where they will be trapped as previously described. The trigger stroke will be internally limited so that it will not  
20 achieve the latched condition in which the cycle began. Releasing the trigger moves the needle carrier 406 forward, separating the needles from blocks 410. The entire device can now be removed, drawing sutures through the leaflets as previously described. The distal tip of the device 400 is rotatable relative to the body 416 for precise angular positioning of the ports 402 while maintaining a  
25 comfortable handle position for the user.

The present invention may be embodied in other specific forms without departing from its spirit, and the described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the claims and their equivalents rather than by the foregoing  
30 description.

**WHAT IS CLAIMED IS:**

1. An apparatus for the approximation of two pieces of tissue,  
comprising:  
a probe with a distal tip having at least one lumen and adapted to  
approach the tissue pieces to be joined;  
5 at least one vacuum port adjacent the distal tip of the probe, the at  
least one port being in fluid communication with a vacuum source via the at  
least one lumen so as to enable the probe to stabilize adjacent pieces of  
tissue.
- 10 2. The apparatus of claim 1, further comprising a suture-based tissue  
fastener coupled to the probe for fastening the two pieces of tissue.
3. The apparatus of claim 2, wherein the tissue fastener comprises a  
toggle and a suture thread attached to the toggle.
- 15 4. The apparatus of claim 3, further comprising a needle having a  
lumen and a pusher slidably disposed at a proximal end of the needle  
lumen, the tissue toggle and suture thread are housed within the distal end  
of the needle lumen to be urged from the distal end of the needle by the  
pusher.
- 20 5. The apparatus of claim 4, further comprising a delivery lumen  
having an opening on a distal face of the probe, wherein the delivery lumen  
receives and deploys the needle, and the distal end of the needle pierces  
through the tissue to be fastened.
6. The apparatus of claim 2, wherein the suture-based tissue fastener  
includes a needle attached to a suture thread.
- 25 7. The apparatus of claim 6, further comprises an extension member  
having a distally-directed frame coupled to a distal end of the probe,  
wherein the extension member is extendable and retractable and the frame  
defines a space, the needle being pivotally coupled to the frame and  
residing within the space.

8. The apparatus of claim 7, wherein the needle is deployed on a blind side of the tissue such that the needle pierces the blind side and exits through the front side of the tissue.
- 5 9. The apparatus of claim 8, wherein the probe further includes a needle receiver, wherein the needle is directed into the needle receiver.
10. The apparatus of claim 1, further comprising a clip coupled to the probe for fastening the two pieces of tissue.
11. The apparatus of claim 10, wherein the clip comprises an integral spring portion having two arms, each of the arms having one or more barbs.
- 10 12. The apparatus of claim 11, wherein distal ends of the arms are tapered to enable the clip to pierce the pieces of tissue and the arms are overlapping when in a closed position.
13. The apparatus of claim 10 wherein the clip comprises an integral spring portion having two arms, wherein the arms have tapered distal ends extending inwardly to pierce and lockingly secure the pieces of tissue, and wherein a gap exists between midportions of the arms when the clip is in a closed position.
- 15 14. The apparatus of claim 10, wherein the probe further comprises:  
an internal lumen;  
20 a pusher slidably received within the internal lumen; and  
a sleeve disposed between the pusher and an internal wall of the internal lumen;  
wherein the clip is housed within the sleeve in an open position.
15. The apparatus of claim 14, wherein movement of the pusher in the distal direction causes the clip to pierce the pieces of tissue and wherein the clip automatically springs to its closed position when the clip disengages from the probe causing the pieces of tissue to be compressed together.
- 25 16. The apparatus of claim 1, wherein the probe comprises a catheter

tube having at least one lumen connecting the at least one vacuum port to the vacuum source.

5        17.     The apparatus of claim 16, wherein the catheter has sufficient length, steerability and maneuverability to reach the tissue pieces from a peripheral insertion site.

18.     The apparatus of claim 17, wherein the catheter has sufficient length, steerability and maneuverability to reach the tissue pieces from an insertion site at the femoral artery.

10       19.     The apparatus of claim 17, wherein the catheter has sufficient length, steerability and maneuverability to reach the tissue pieces from an insertion site at the brachial artery.

20.     The apparatus of claim 1 further comprising a staple coupled to the probe for fastening the two pieces of tissue.

15       21.     The apparatus of claim 20 wherein the staple comprises a bridge portion and at least gripping one arm on either side of the bridge portion.

22.     The apparatus of claim 21 further comprising two gripping arms on either side of the bridge portion.

20       23.     The apparatus of claim 21 wherein the gripping arms are curled in a semi-circle upward from the plane of the bridge portion and terminate in sharp points approximately in the plane of the bridge portion.

24.     The apparatus of claim 1 further comprising at least one echogenic member at or near the at least one vacuum ports to enhance echo visualization.

25       25.     The apparatus of claim 1 further comprising at polymer coating which can be wholly or selectively applied at or near the at least one vacuum ports to enhance echo visualization.

26.     An apparatus for the approximation of two pieces of tissue,

comprising:

a probe with a distal tip having at least one lumen and adapted to approach the tissue pieces to be joined; and

a clip coupled to the probe for fastening the two pieces of tissue.

5        27.    The apparatus of claim 26, wherein the clip comprises an integral spring portion having two arms, each of the arms having one or more barbs.

28.    The apparatus of claim 27, wherein distal ends of the arms are tapered to enable the clip to pierce the pieces of tissue and the arms are overlapping when in a closed position.

10       29.    The apparatus of claim 26 wherein the clip comprises an integral spring portion having two arms, wherein the arms have tapered distal ends extending inwardly to pierce and lockingly secure the pieces of tissue, and wherein a gap exists between midportions of the arms when the clip is in a closed position.

15       30.    The apparatus of claim 26, wherein the probe further comprises:  
an internal lumen;  
a pusher slidably received within the internal lumen; and  
a sleeve disposed between the pusher and an internal wall of the  
internal lumen;

20                wherein the clip is housed within the sleeve in an open position.

31.    The apparatus of claim 30, wherein movement of the pusher in the distal direction causes the clip to pierce the pieces of tissue and wherein the clip automatically springs to its closed position when the clip disengages from the probe causing the pieces of tissue to be compressed together.

25       32.    An apparatus for the approximation of two pieces of tissue, comprising:

a probe with a distal tip having at least one lumen and adapted to approach the tissue pieces to be joined; and

a mechanical tissue stabilizer coupled to a distal end of the probe,



the mechanical tissue stabilizer comprising:

a distally-directed frame defining a space therein; and

rotatable and linearly extendable capture hooks disposed within the

space, the hooks being folded flat within the space and rotatably and

5       slidingly coupled to the probe such that the hooks may be rotated and  
retracted to a capture position, and the pieces of tissue are clamped between  
distal ends of the hooks and the shoulders of the probe.

33.     The apparatus of claim 32, further comprising a suture-based tissue  
fastener coupled to the probe for fastening the pieces of tissue.

10       34.     The apparatus of claim 33, wherein the tissue fastener includes a  
toggle and a suture thread attached to the toggle.

35.     The apparatus of claim 34, wherein the tissue toggle and suture  
thread are housed in a lumen of a needle, a pusher is slidingly disposed at a  
proximal end of the needle lumen, and the tissue toggle and suture thread  
15       are housed within the distal end of the needle lumen to be urged from the  
distal end of the needle by the pusher.

36.     The apparatus of claim 35, further comprising a delivery lumen  
having an opening on a distal face of the probe, wherein the delivery lumen  
receives and deploys the needle, and the distal end of the needle pierces  
20       through the tissue to be fastened.

37.     An apparatus for the approximation of two pieces of tissue,  
comprising:

a probe with a distal tip having at least one lumen and adapted to  
approach the tissue pieces to be joined; and

25       means deployable from within the lumen for stabilizing adjacent  
pieces of tissue.

38.     The apparatus of claim 37, further comprising:  
means deployable from within the lumen for fastening adjacent  
pieces of tissue that has been stabilized.

39. The apparatus of claim 37, further comprising:  
means separate from the probe for fastening adjacent pieces of  
tissue that has been stabilized.
40. An apparatus for joining two tissue pieces, comprising:  
5 a probe adapted to be advanced through a body vessel into  
proximity with the tissue pieces, the probe having a distal tip; and  
a pair of vacuum ports adjacent the distal tip of the probe, each  
suitable for stabilizing one of the tissue pieces, the negative pressure  
generated at each port being separately controllable.
41. The apparatus of claim 40, further including a device on the distal  
10 tip for fastening the tissue pieces together.
42. The apparatus of claim 40, further including a device separate from  
the probe for fastening the tissue pieces together.
43. An apparatus for the repair of a mitral valve from the atrial side,  
15 comprising:  
a probe adapted to be advanced through a body vessel and through  
the left atrium into proximity with the mitral valve, the probe having a  
distal tip; and  
a pair of grippers adjacent the distal tip, each gripper adapted to grip  
20 one of the mitral valve leaflets from the atrial side.
44. An apparatus for the repair of a mitral valve from the atrial side,  
comprising:  
a probe adapted to be advanced through a body vessel and through  
the left atrium into proximity with the mitral valve, the probe having a  
25 distal tip; and  
means on the probe for separately holding each of the mitral valve  
leaflets from the atrial side.
45. A method of repairing a mitral valve from the atrial side,  
comprising:

without arresting the heart, advancing a probe through a body vessel and through the left atrium into proximity with the mitral valve, the probe having a distal tip; and

5 separately holding each of the mitral valve leaflets from the atrial side with the probe.

46. The method of claim 45, further comprising:  
manipulating one of the mitral valve leaflets with respect to the other to align them.

47. The method of claim 45, further comprising:  
10 fastening the mitral valve leaflets together using a device mounted on the probe.

48. The method of claim 45, further comprising:  
fastening the mitral valve leaflets together using a device separate from the probe.

15 49. A method of repairing a mitral valve having adjacent leaflets comprising:  
providing a catheter having a distal tip, the catheter comprising:  
at least one lumen and at least one vacuum port adjacent the  
distal tip of the catheter, the at least one port being in fluid communication  
20 with the at least one lumen so as to enable the probe to stabilize adjacent leaflets; and

a tissue fastener coupled to the catheter;  
delivering the catheter percutaneously through a peripheral vessel to the mitral valve;  
25 stabilizing the adjacent leaflets; and  
fastening the adjacent leaflets.

50. The method of claim 49 wherein the catheter comprises at least two vacuum ports and wherein the stabilizing step includes the step of applying suction differentially to the adjacent leaflet.

51. The method of claim 49 wherein the catheter is delivered through a femoral artery.

52. The method of claim 49 wherein the catheter is delivered through a brachial artery.

5 53. A kit having devices for the approximation of two pieces of tissue, the kit comprising:

a catheter having sufficient length, steerability and maneuverability to reach the tissue pieces from a peripheral insertion site; and  
a tissue fastener coupled to the catheter.

10 54. The kit of claim 53 wherein the catheter comprises a distal tip, at least one lumen, and at least one vacuum port adjacent the distal tip of the catheter;

the catheter vacuum port being in fluid communication with a vacuum source via the at least one lumen so as to enable the probe to  
15 stabilize adjacent pieces of tissue.

55. An apparatus for the approximation of two pieces of tissue, comprising:

a probe with a distal tip having at least one lumen and adapted to approach the tissue pieces to be joined;

20 two or more vacuum ports adjacent the distal tip of the probe, the ports being in separate fluid communication with a vacuum source via the at least one lumen so as to enable the probe to differentially stabilize adjacent pieces of tissue.

25 56. The apparatus of claim 55 further comprising a two or more vacuum ports and a tissue fastening device wherein the tissue fastening device comprises a carrier centrally disposed between the vacuum ports at the distal end of the probe.

57. The apparatus of claim 56 wherein the carrier is configured to be extended from the distal tip and retracted back towards the distal tip so that

the tissue fastening device can be placed on a first side of the tissue while the vacuum ports remain on a second side of the tissue.

58. The apparatus of claim 57 wherein the tissue fastening device comprises needles which are pivotably mounted on the carrier.

5 59. The apparatus of claim 58 wherein the vacuum ports further comprise needle catchers which are configured to retain and store the needles in the vacuum ports.

60. The apparatus of claim 56 wherein the tissue fastening device is a suture based tissue fastening device.

10 61. The apparatus of claim 55 wherein the probe has a longitudinal axis and the vacuum ports have vacuum surfaces which are angled between zero and ninety degrees relative to a plane normal to the longitudinal axis.

62. The apparatus of claim 61 wherein the vacuum surfaces are angled between fifteen and forty degrees relative to a plane normal to the  
15 longitudinal axis.

63. The apparatus of claim 62 wherein the vacuum surfaces are angled at about twenty-five degrees relative to a plane normal to the longitudinal axis.

64. The apparatus of claim 55 wherein the probe is cylindrical in shape  
20 and the vacuum ports are approximately D shaped.

65. The apparatus of claim 64 wherein the corners of the D shaped ports where the arc meets the straight portion at acute angles have been filled in.

66. The apparatus of claim 64 wherein the vacuum ports have barriers recessed below the perimeter of the D.

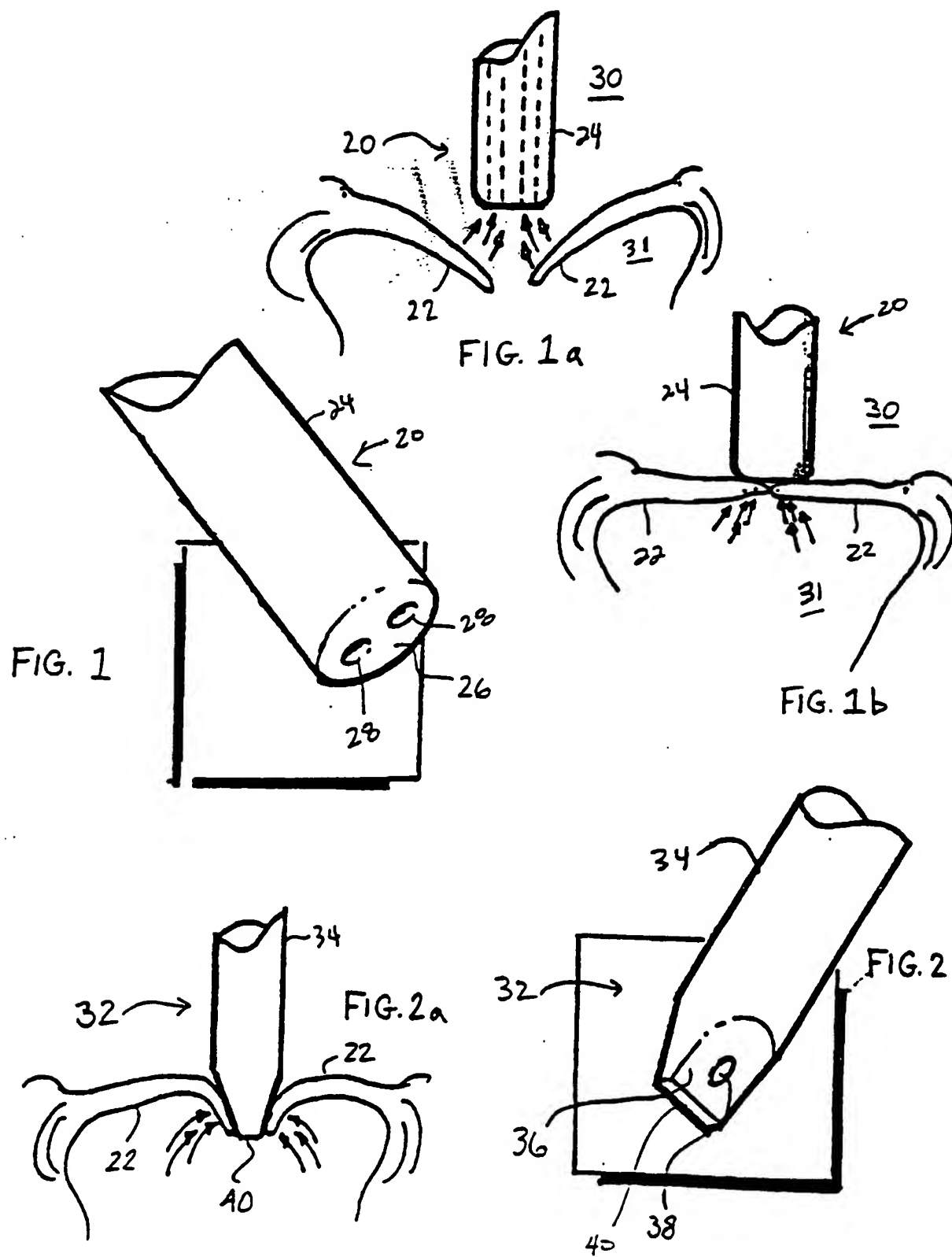
25 67. The apparatus of claim 55 further comprising a proximal handpiece portion having individual vacuum port controls.

68. The apparatus of claim 67 wherein the handpiece portion connects the vacuum source to the vacuum ports via separate vacuum lines.

5 69. The apparatus of claim 68 wherein the handpiece portion further comprises two pinch valves, each pinch valve capable of constricting one of the vacuum lines to permit differential control of access to the vacuum source.

10 70. The apparatus of claim 67 wherein the handpiece portion is configured like a pistol having a shaft portion and a handle portion and the vacuum port controls are located at the back of shaft portion and at the top of handle portion like a pistol hammer.

71. The apparatus of claim 67 wherein the handpiece portion is configured like a pistol having a shaft portion and a handle portion and the vacuum port controls are located below the shaft portion and in front of the handle portion like a pistol trigger.



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FIG. 3a.

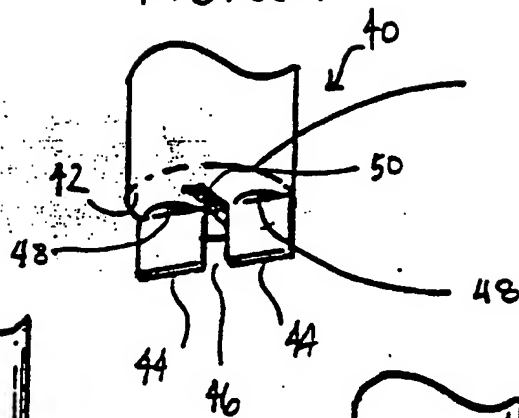


FIG. 3b

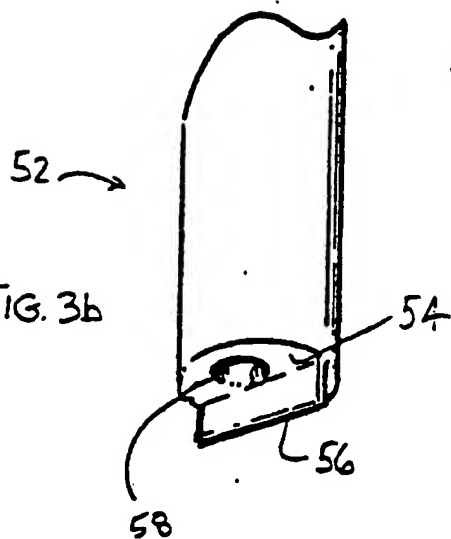


FIG. 3c

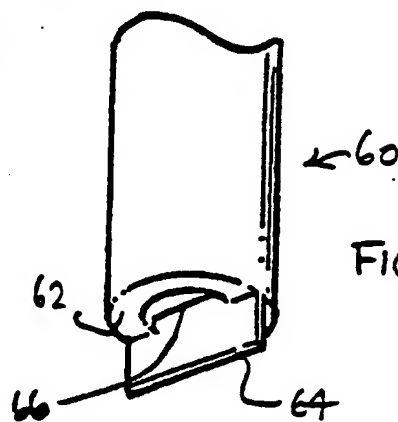


FIG. 3d

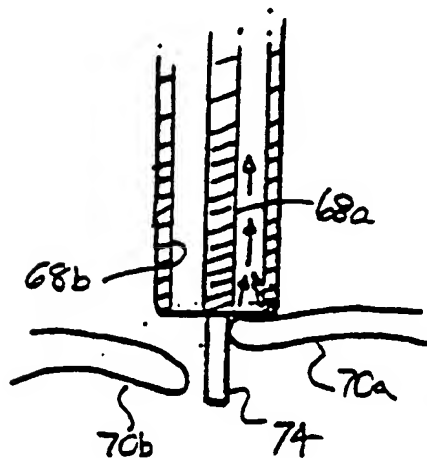
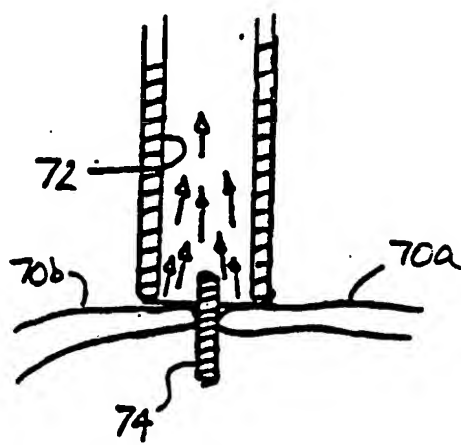
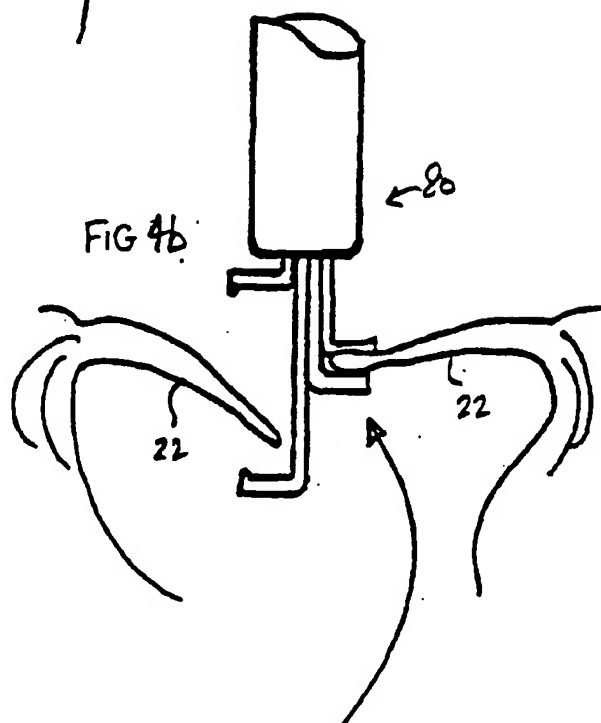
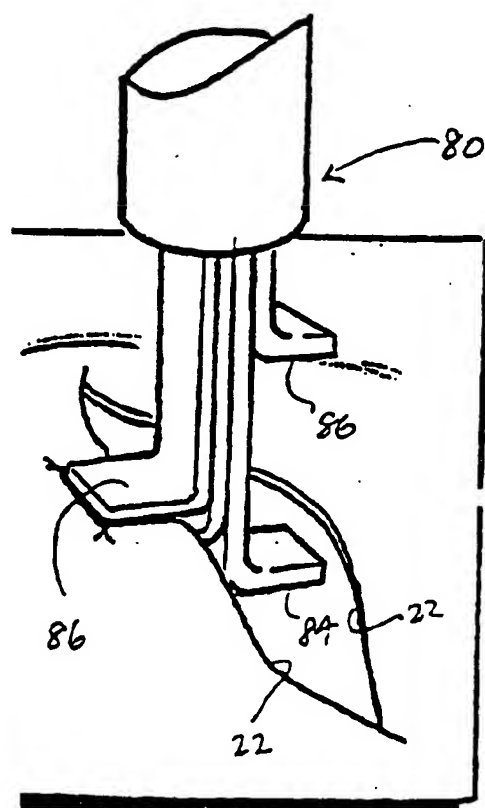
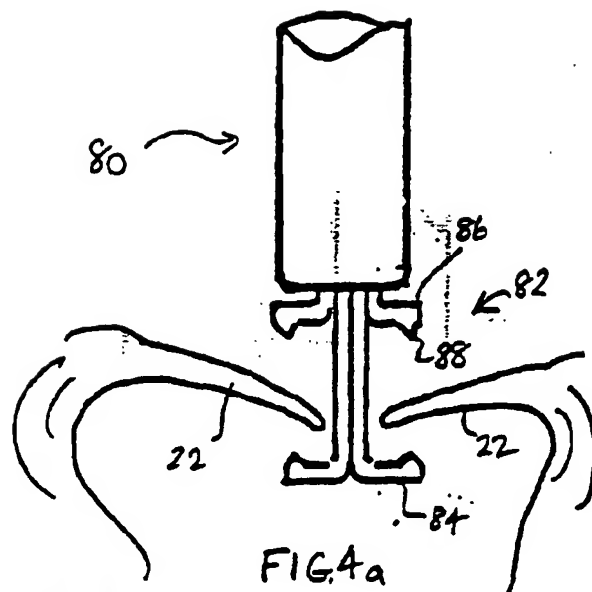


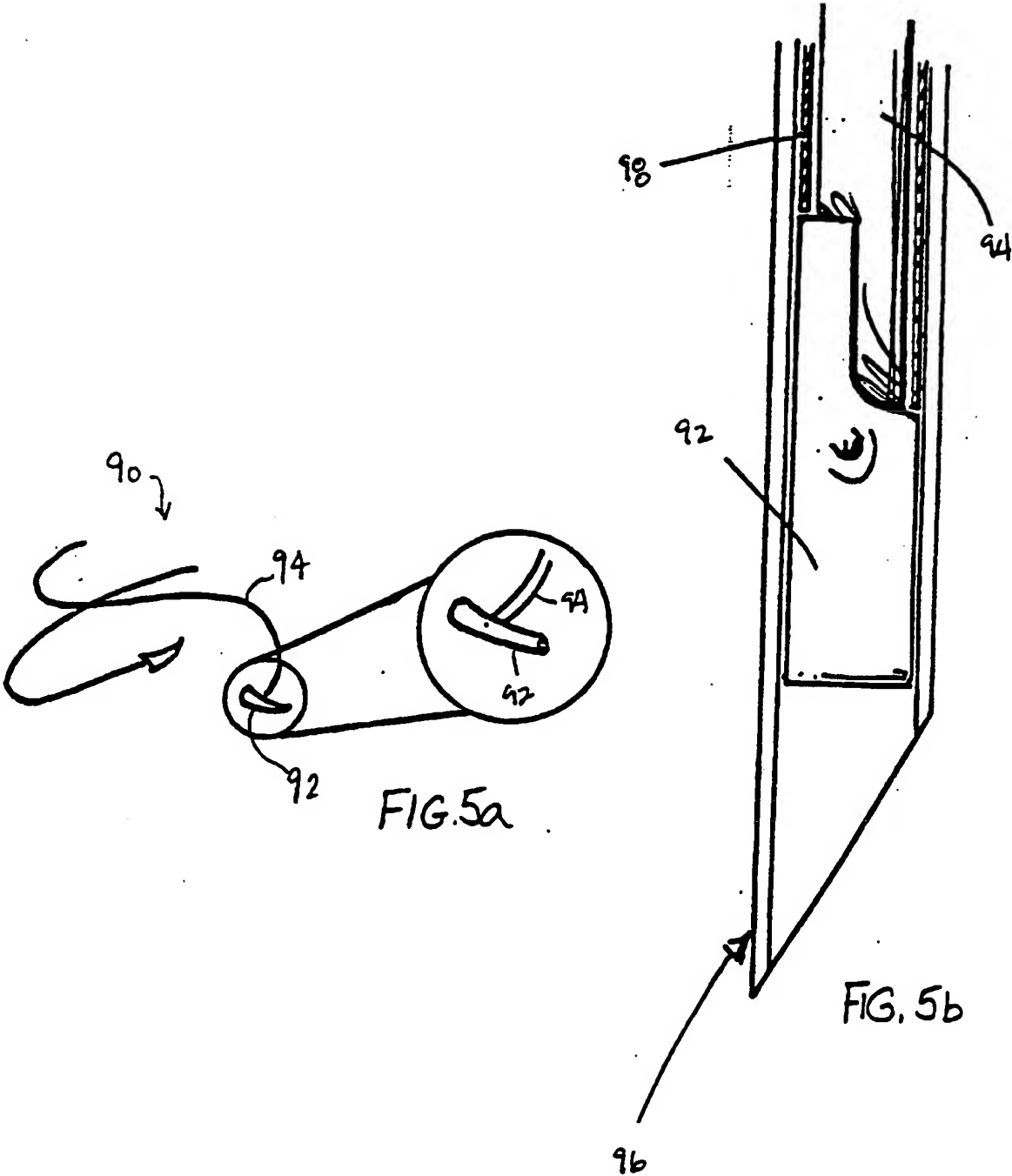
FIG. 3e



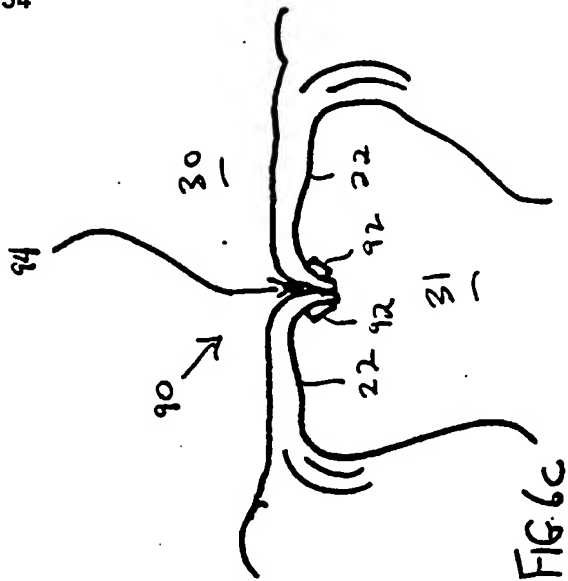
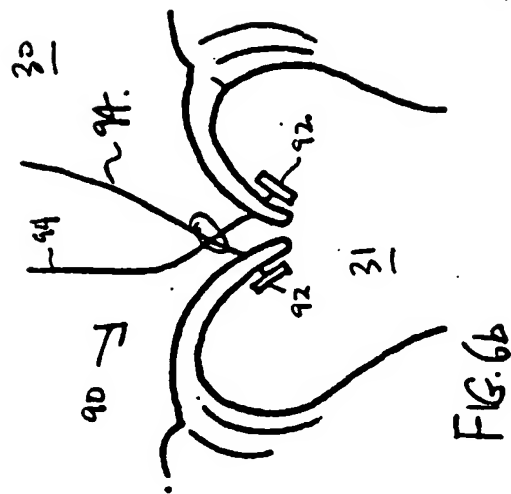
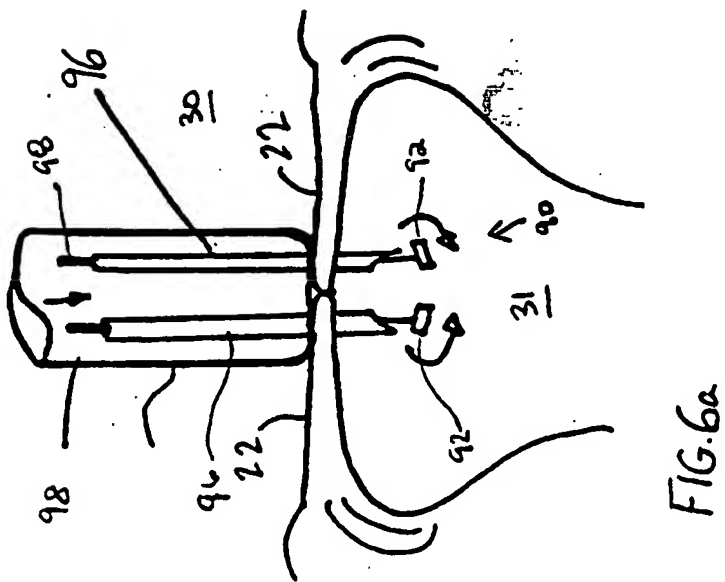


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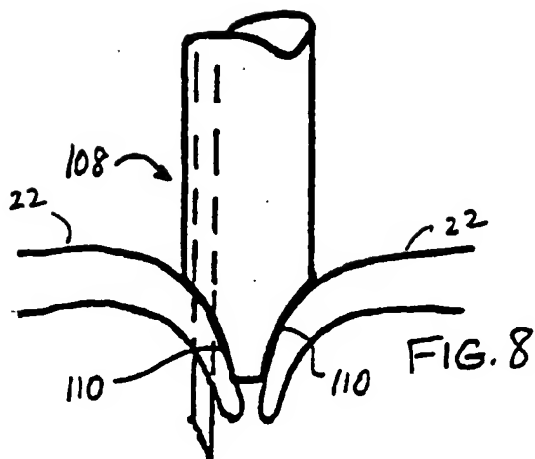
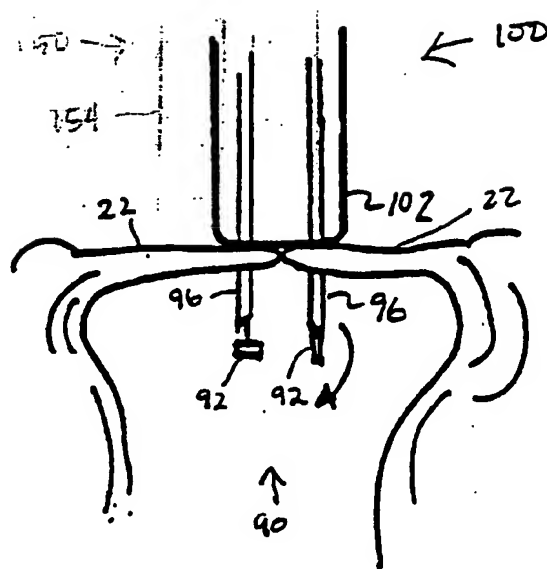
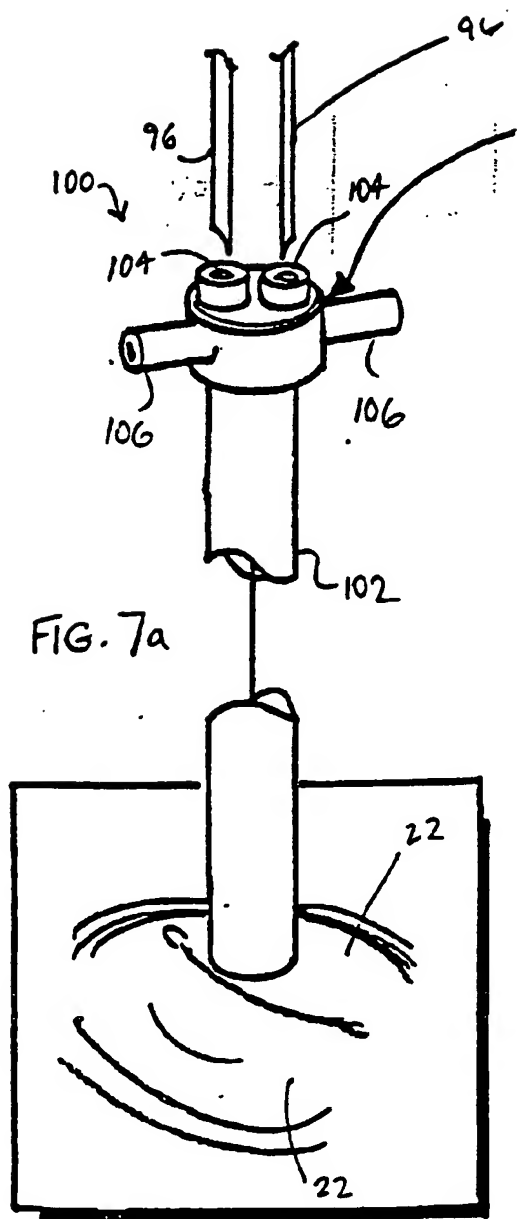




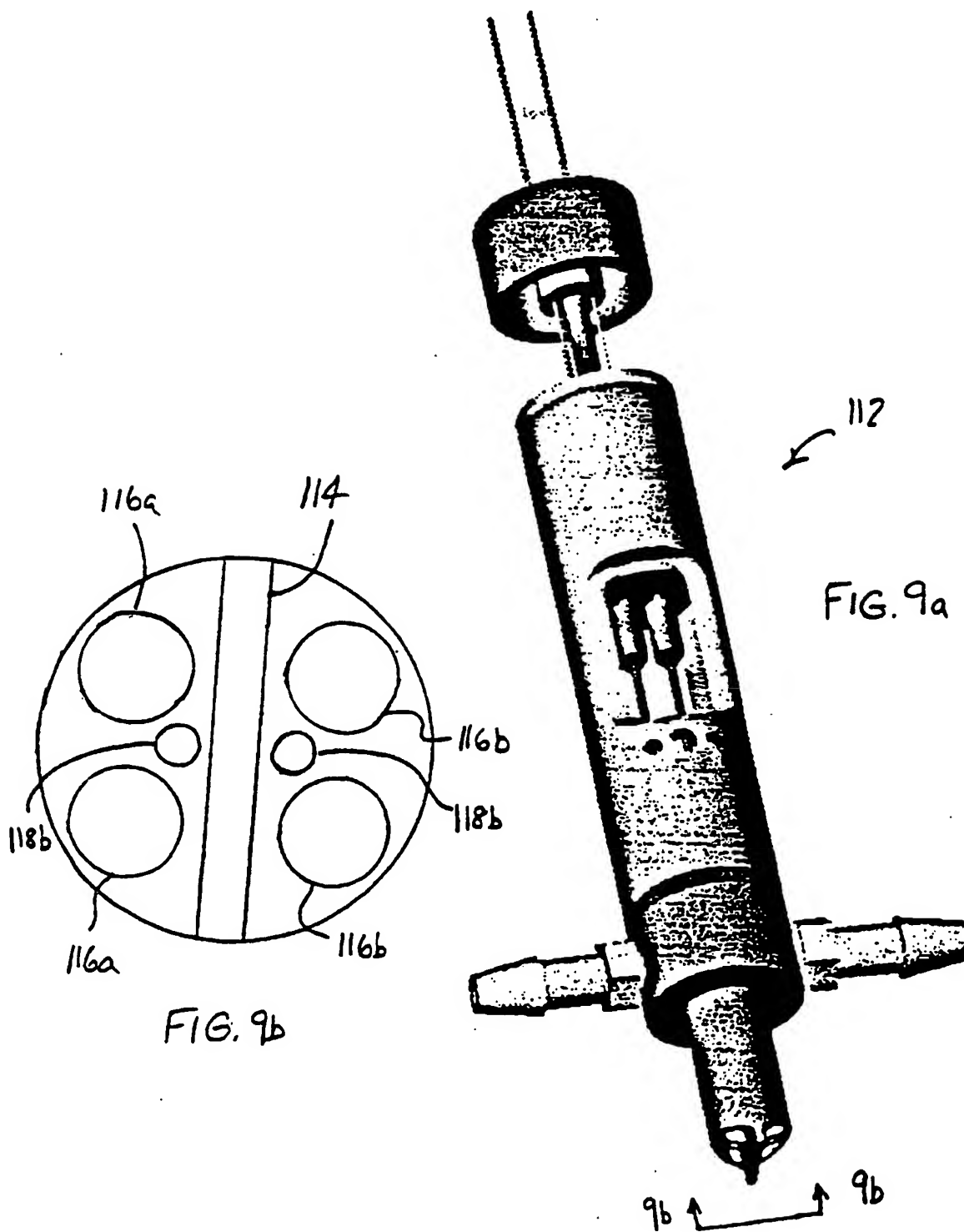
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FIG. 10a



FIG. 10b

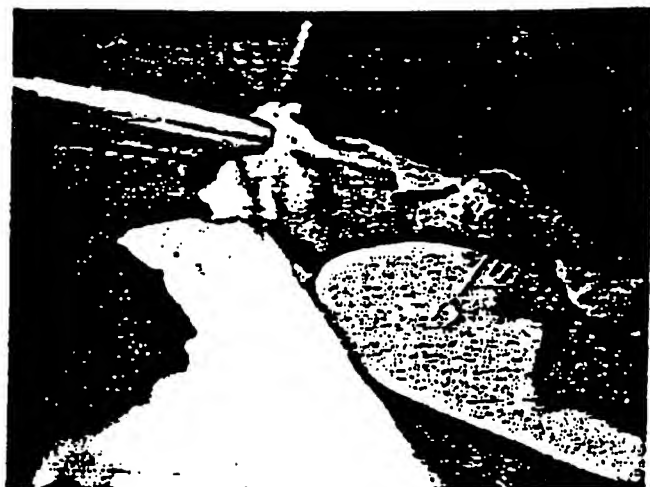


FIG. 10c

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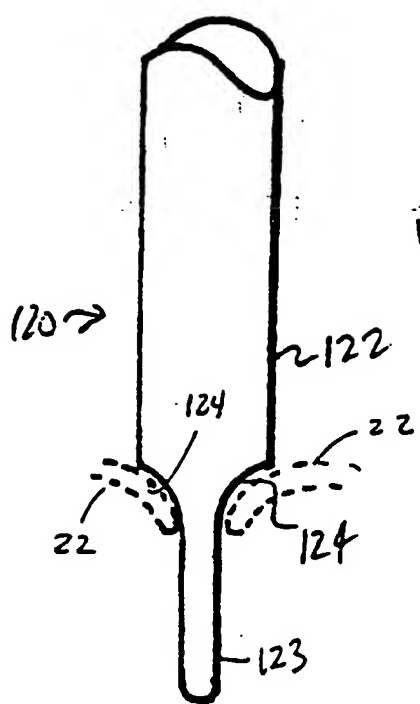


FIG. 11a

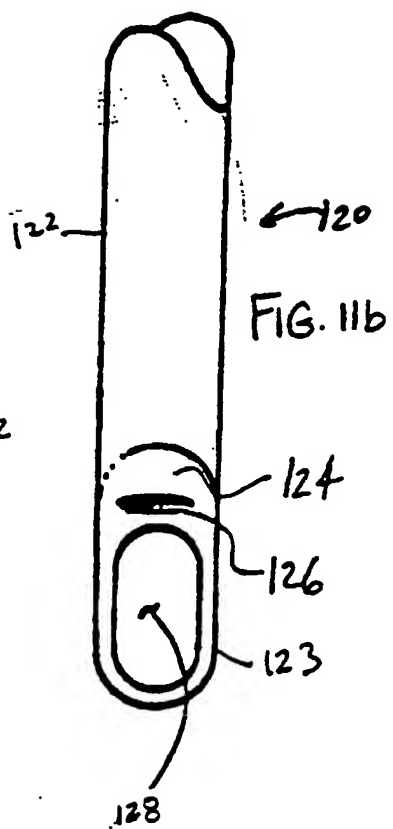


FIG. 11b

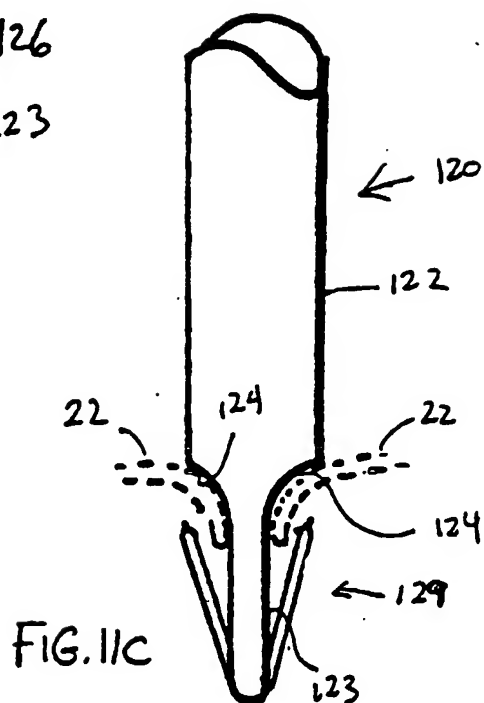
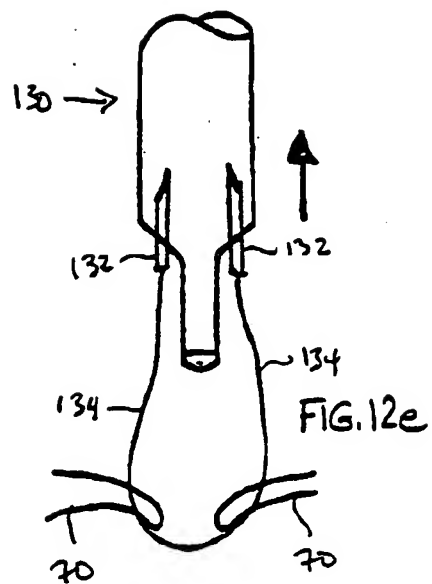
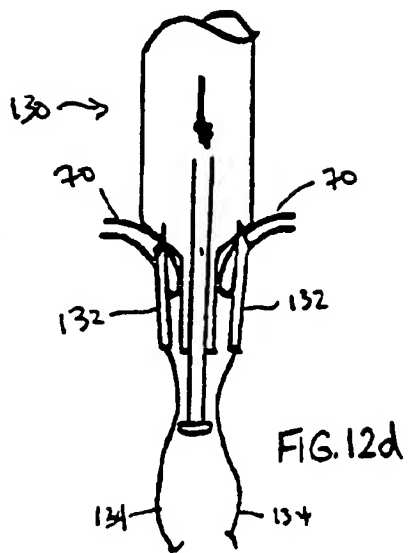
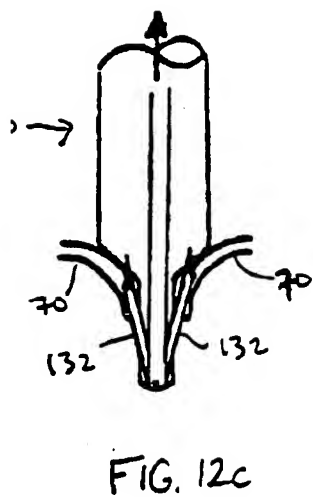
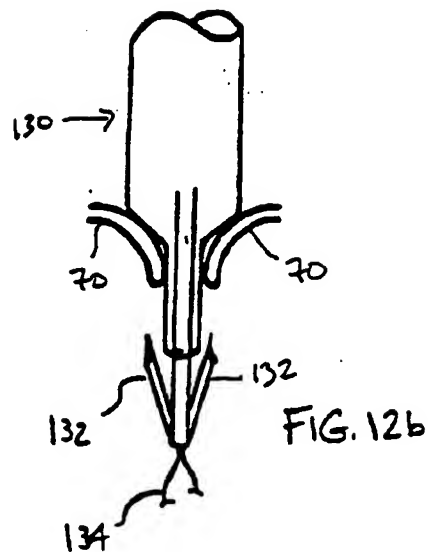
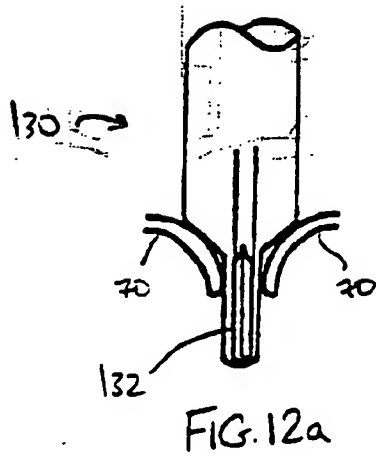


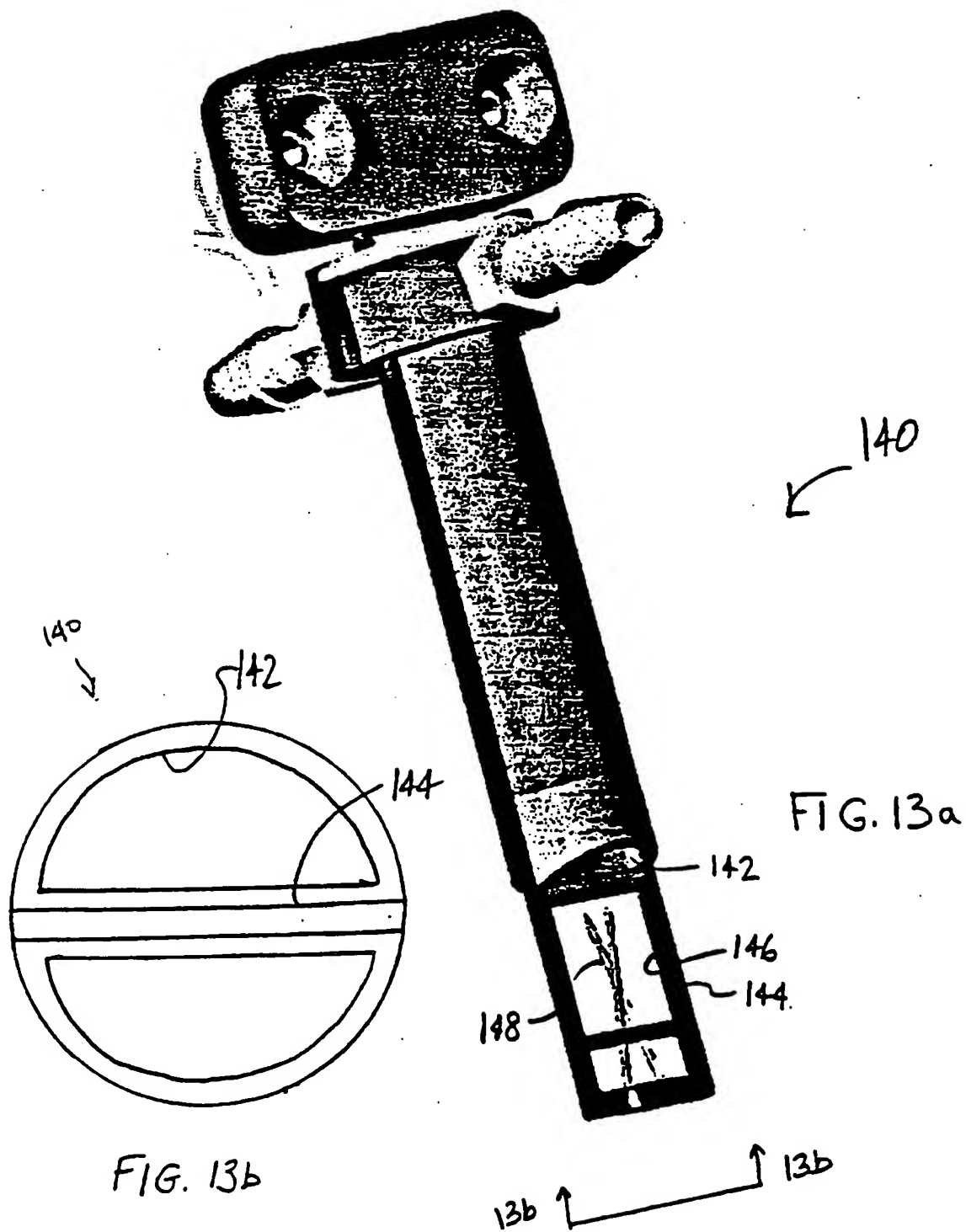
FIG. 11c

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Fig. 14a

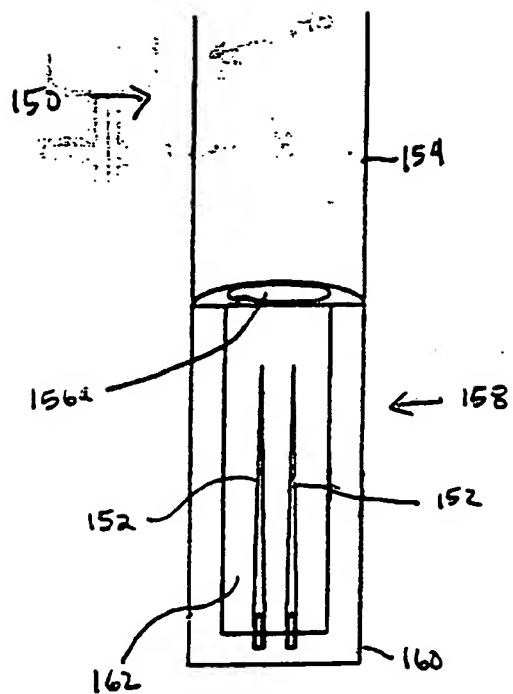
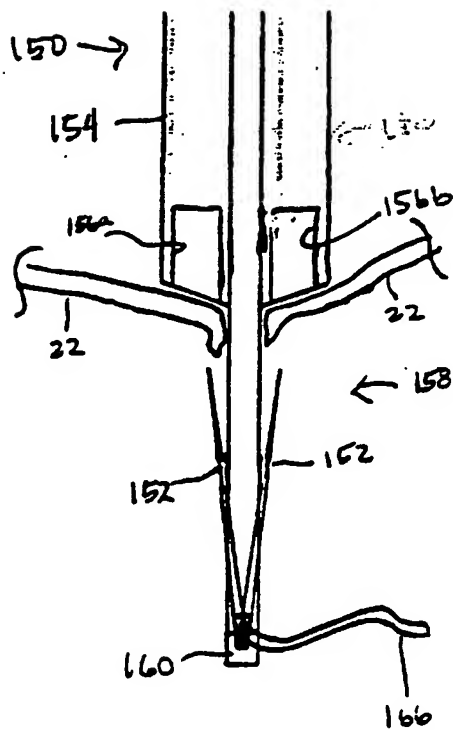


Fig. 14b



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Fig. 15a

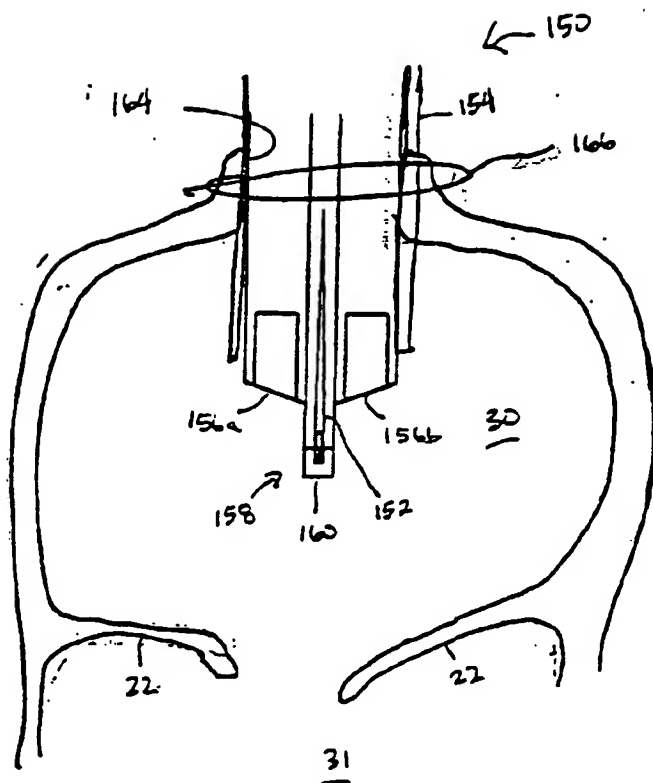
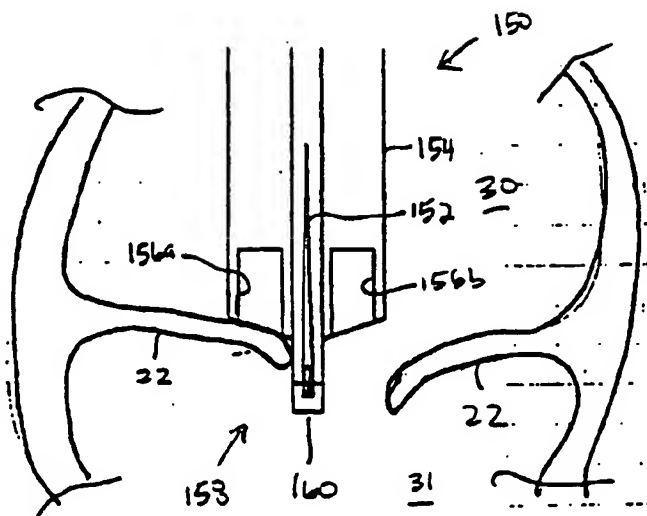


Fig. 15b



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Fig. 15c

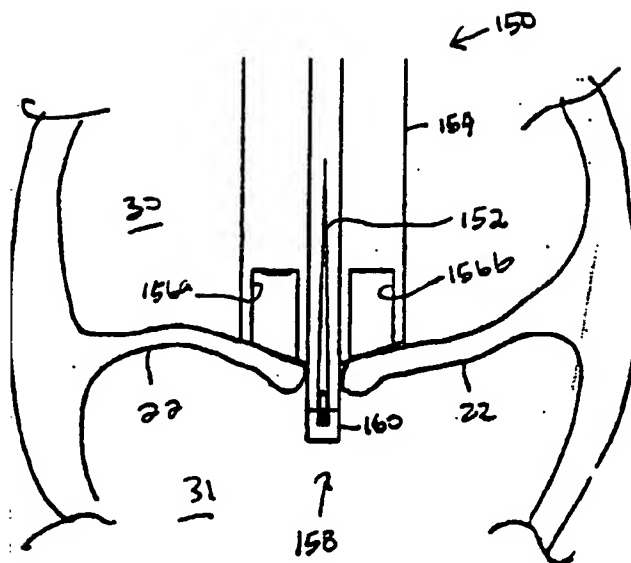
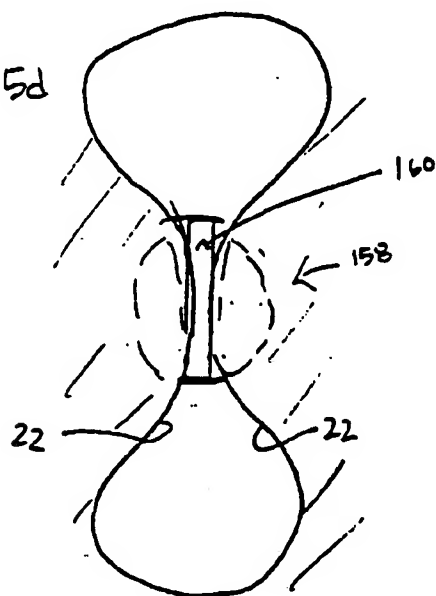


Fig. 15d



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Fig. 15e

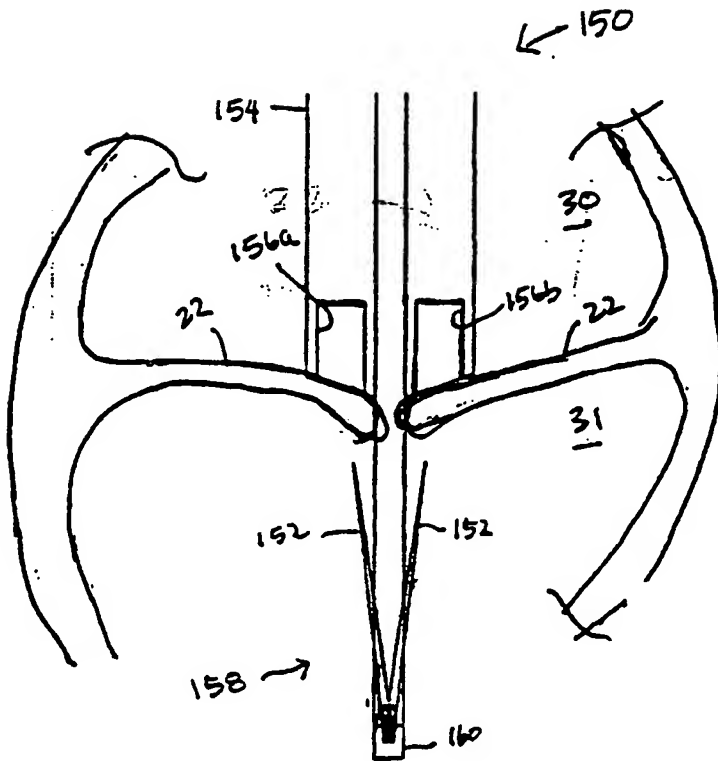


Fig. 15f

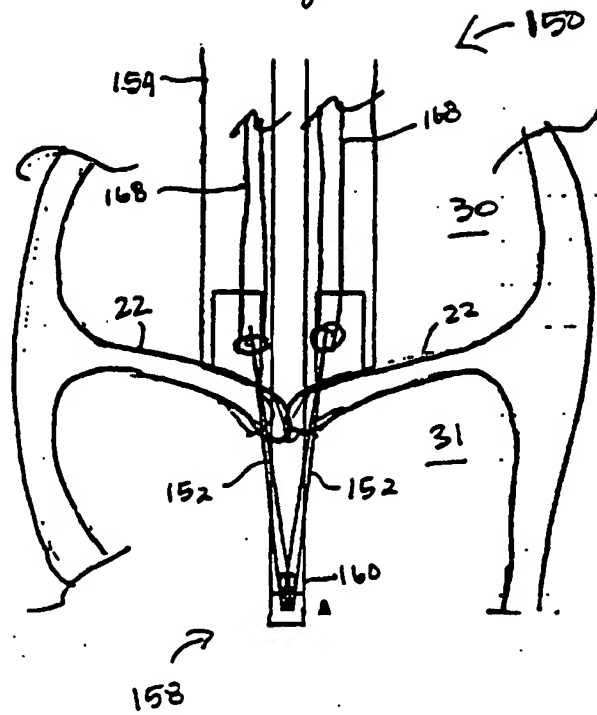


Fig. 15g

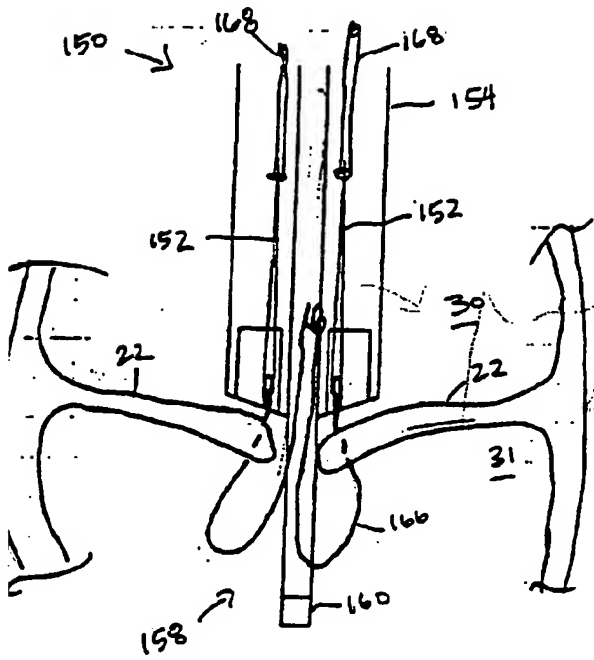
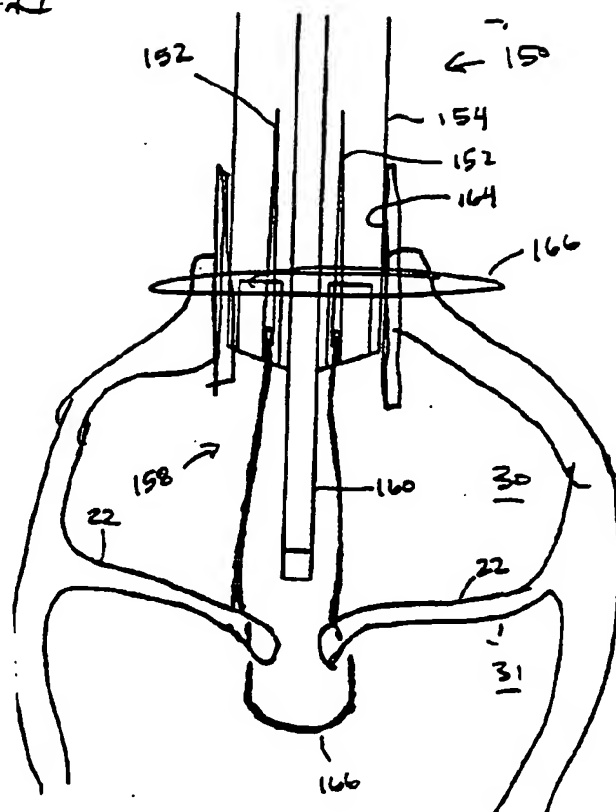
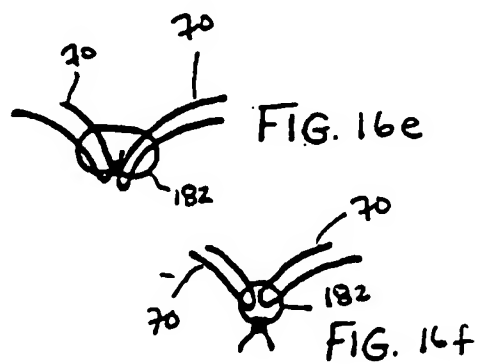
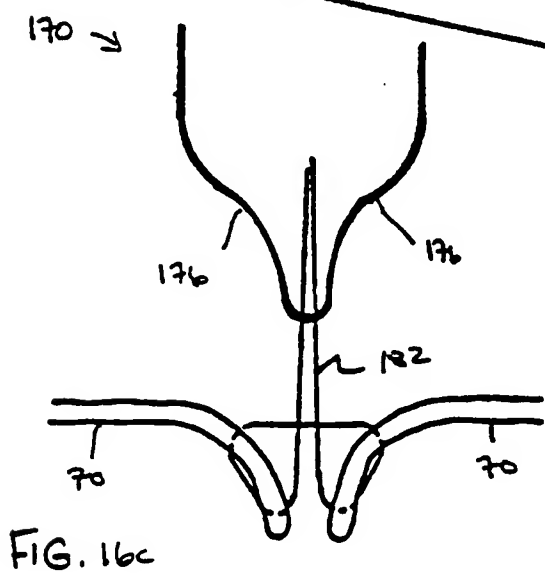
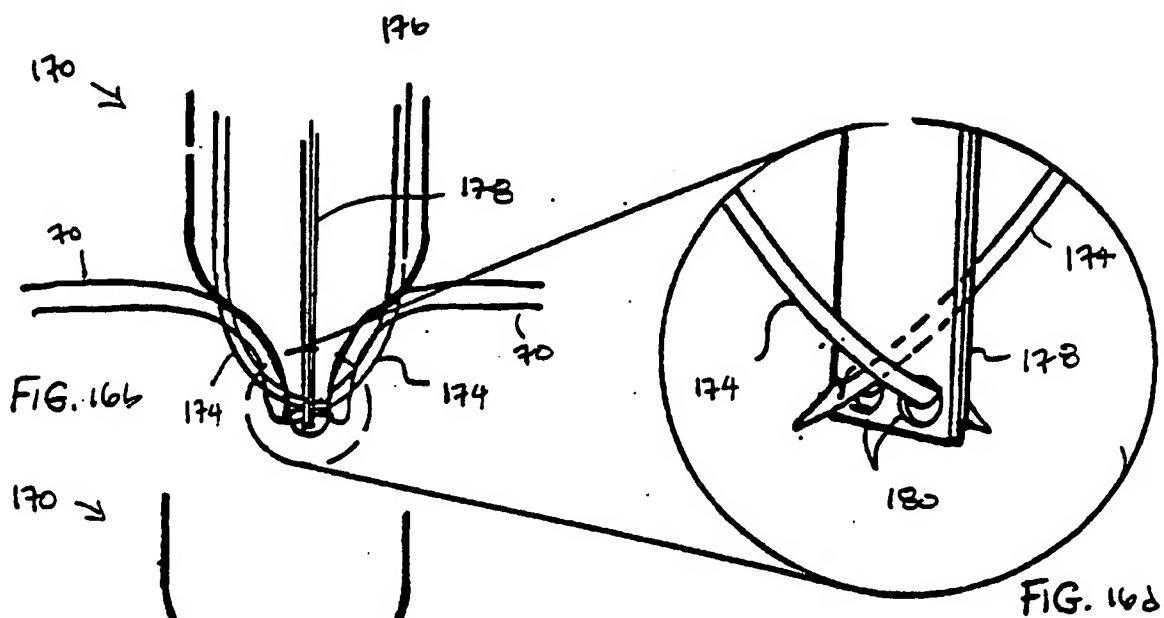
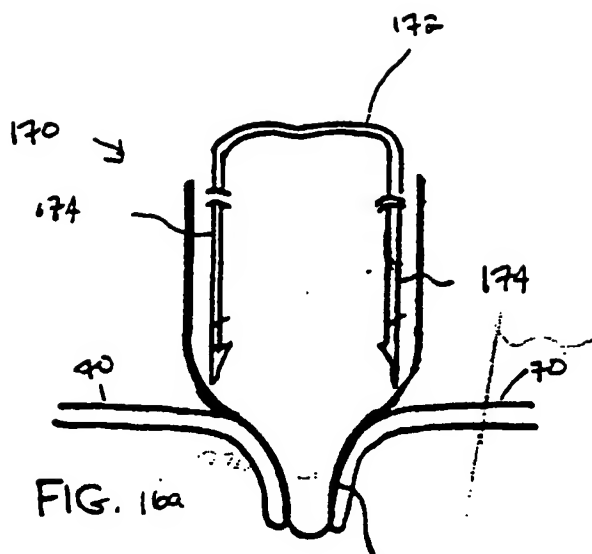


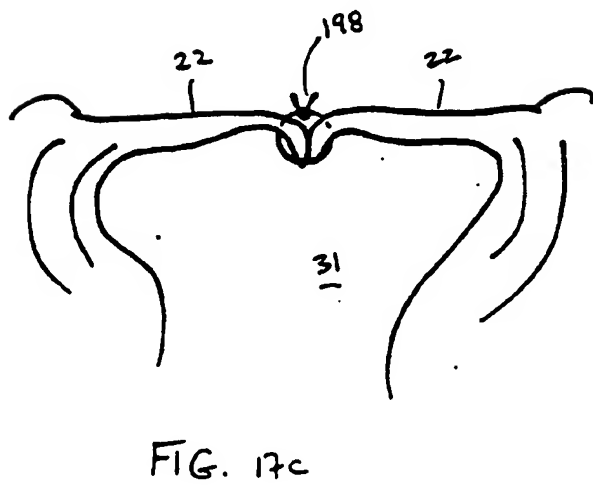
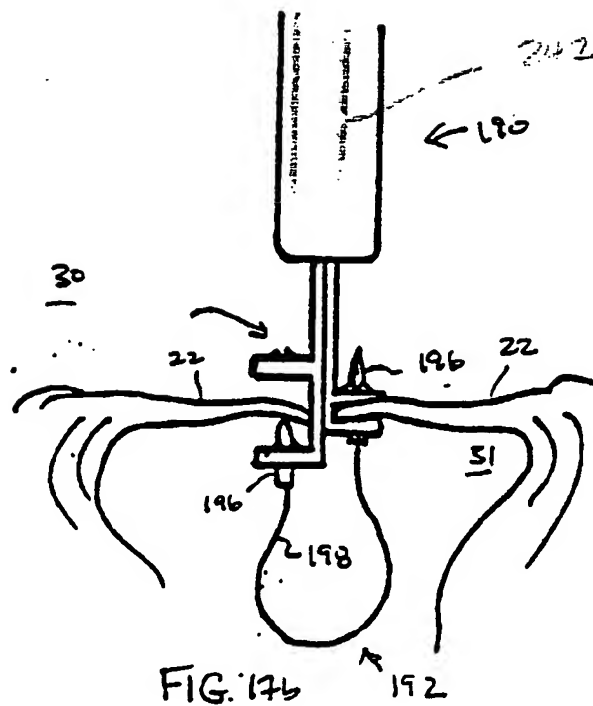
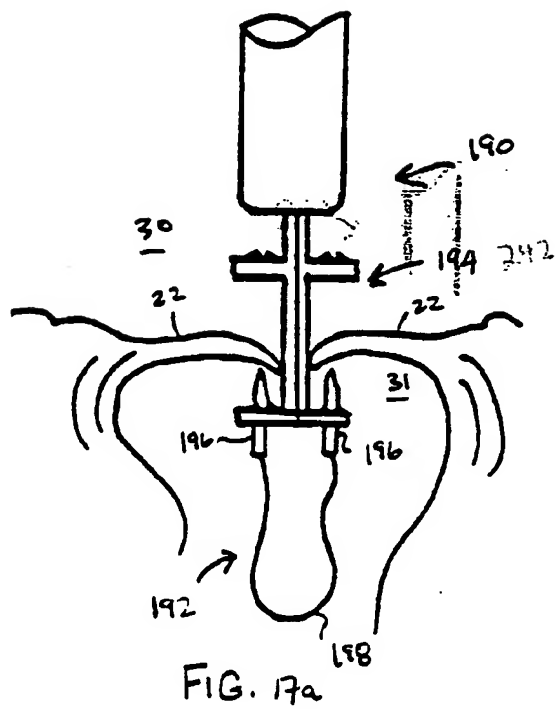
Fig. 15h



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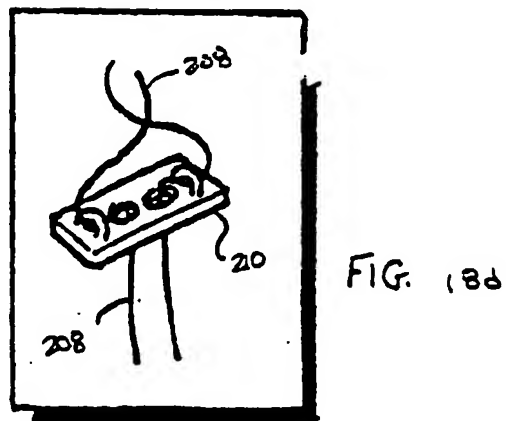
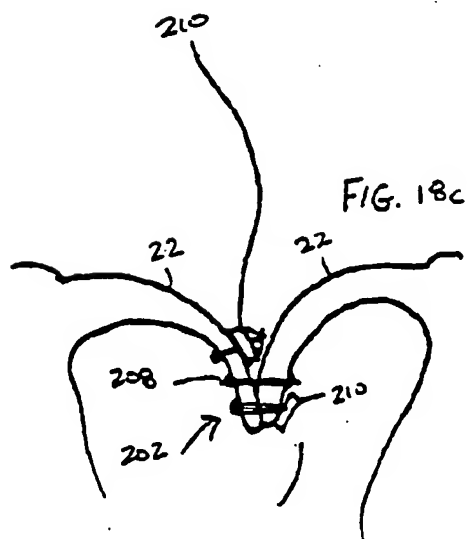
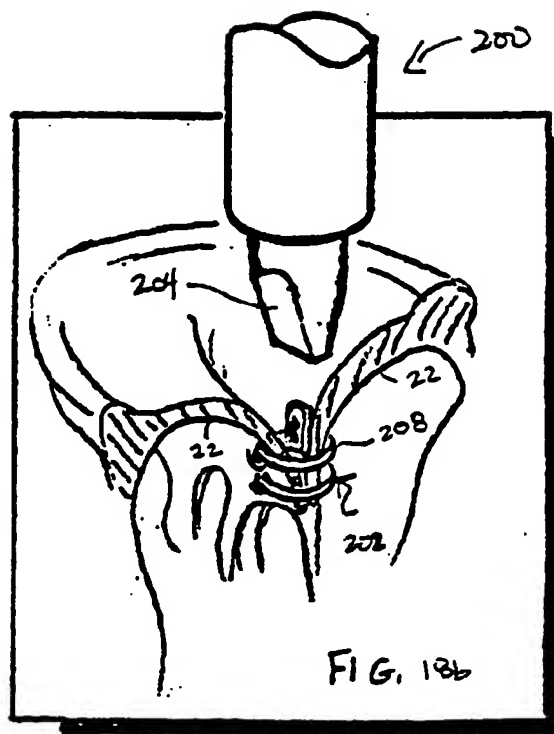
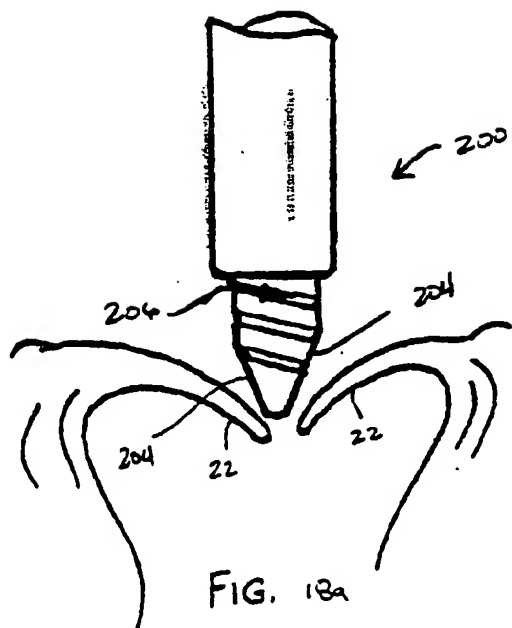


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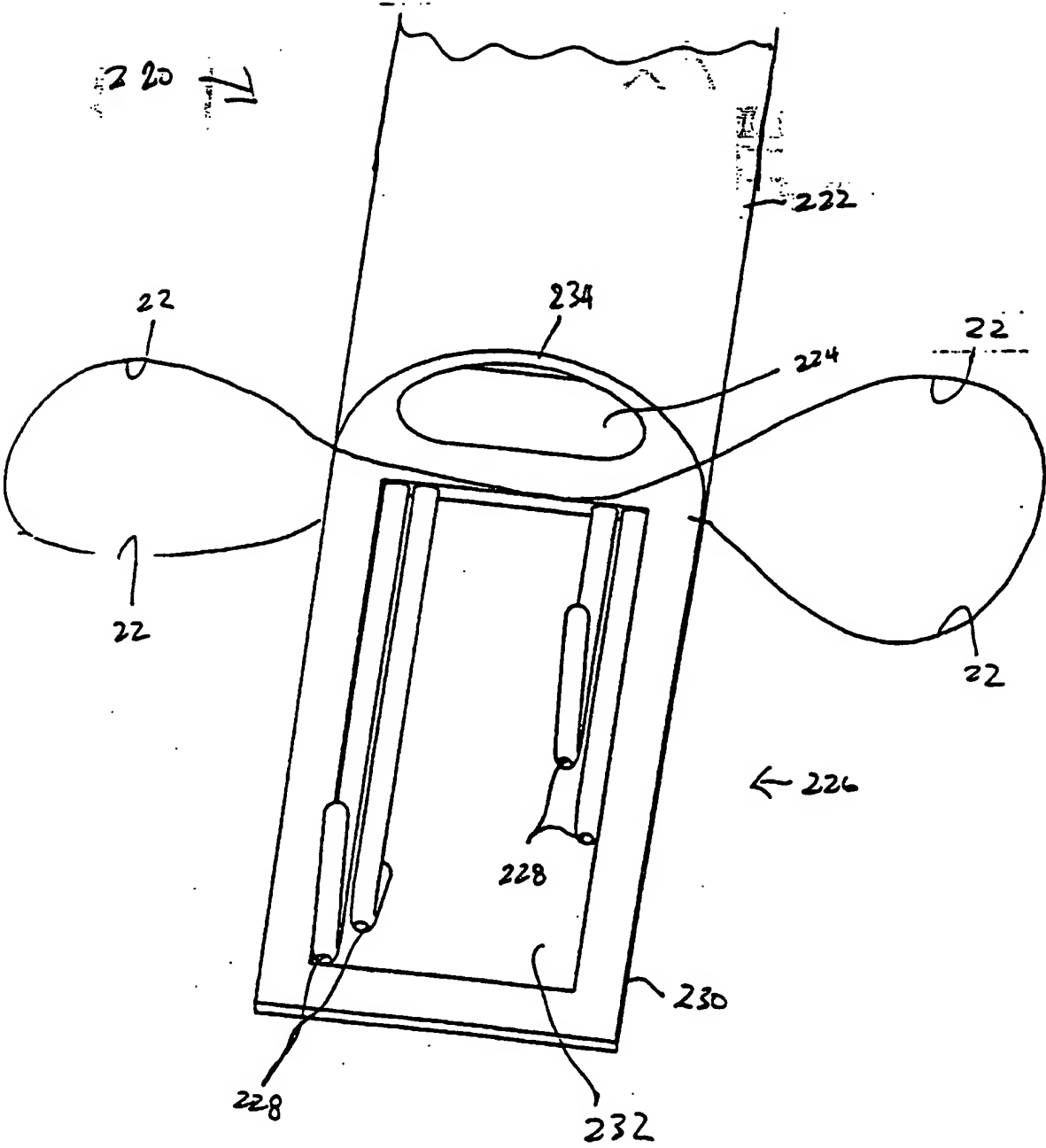
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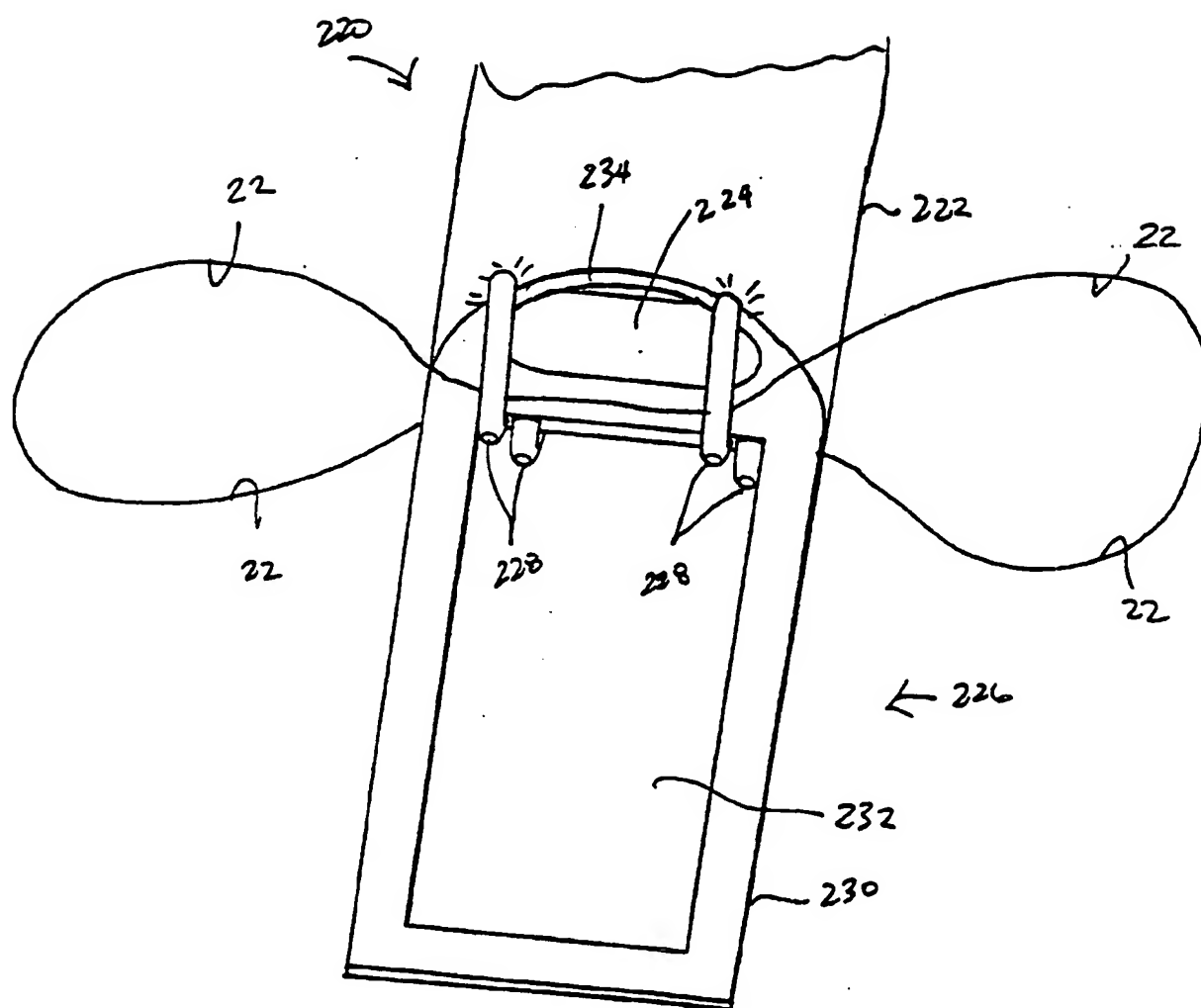
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Fig. 19b



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Fig. 19c





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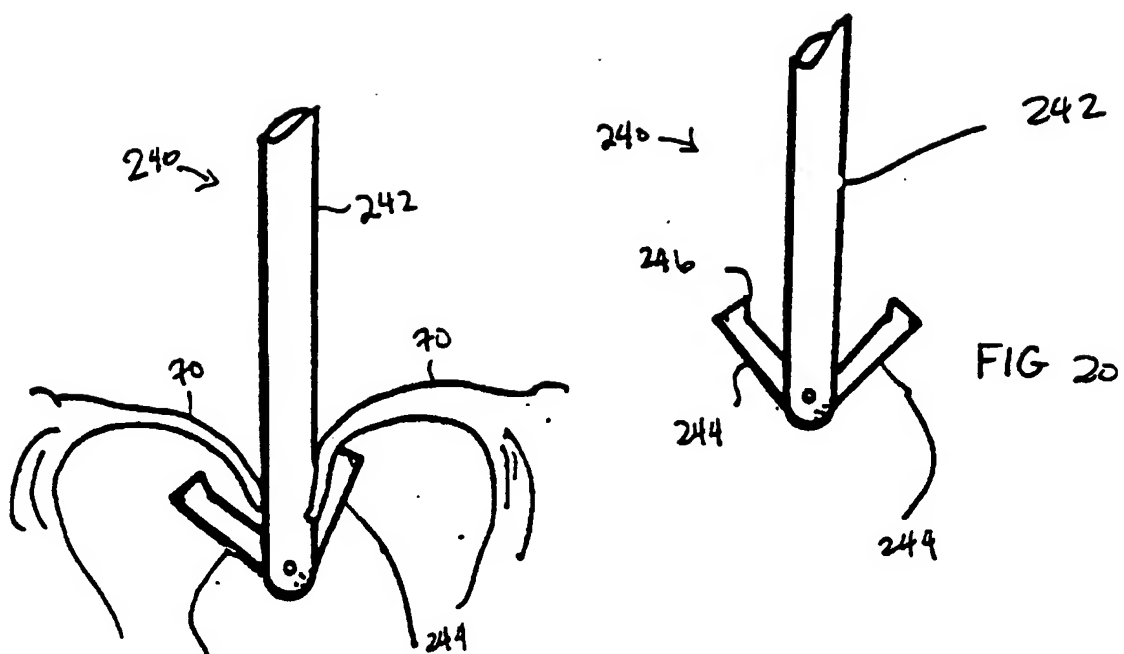


FIG. 21a

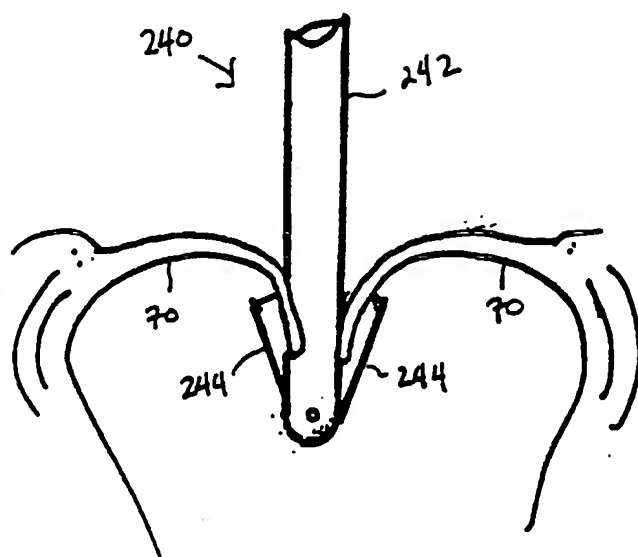
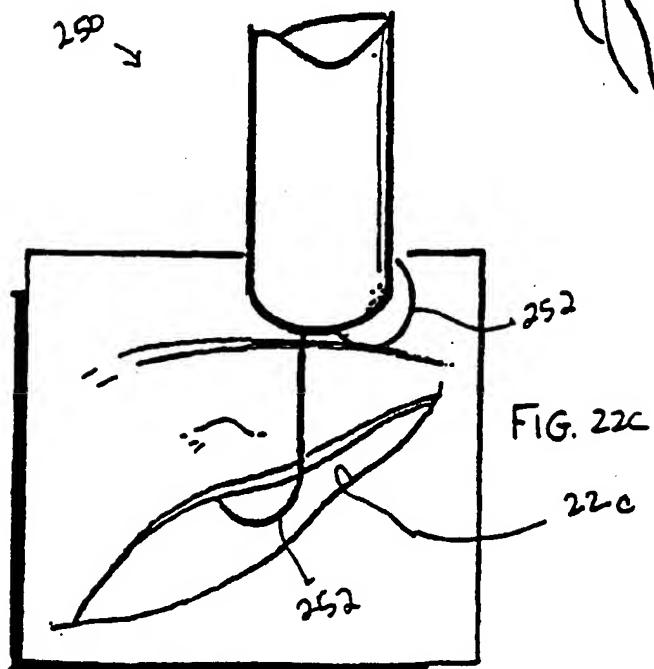
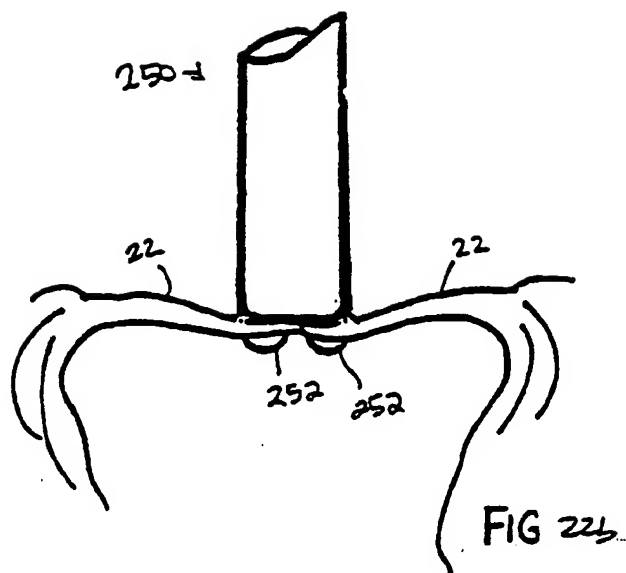
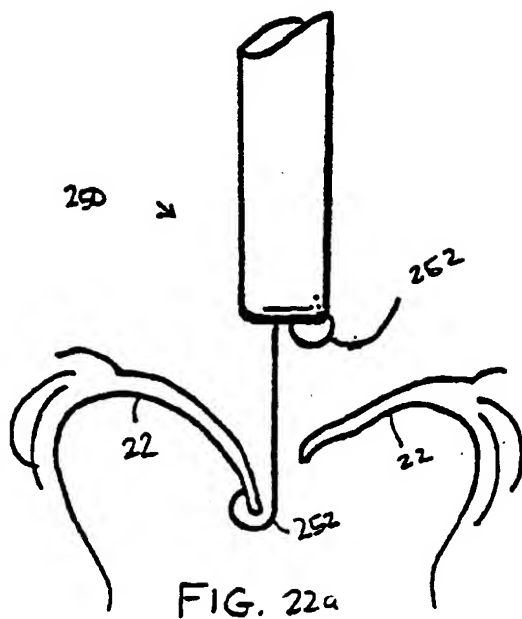
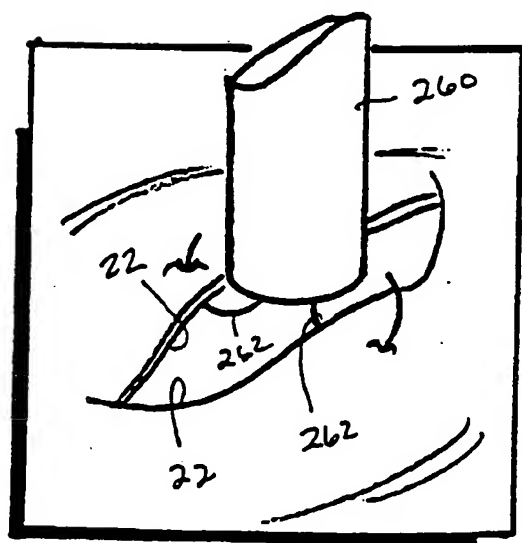
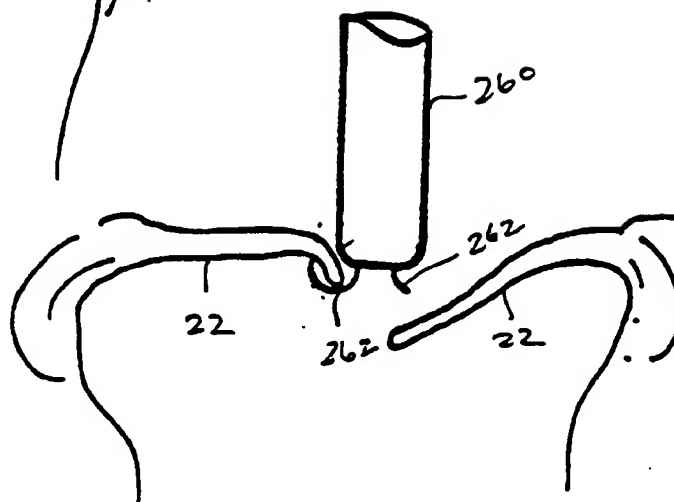
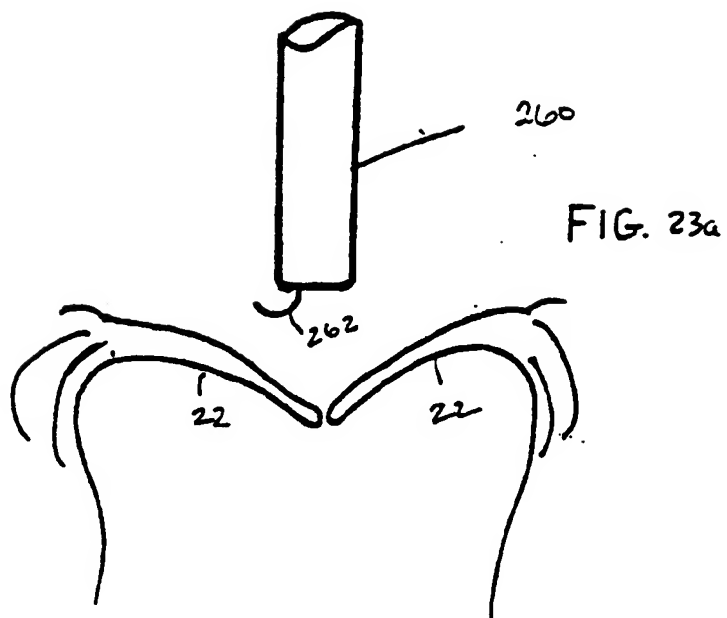


FIG. 21b

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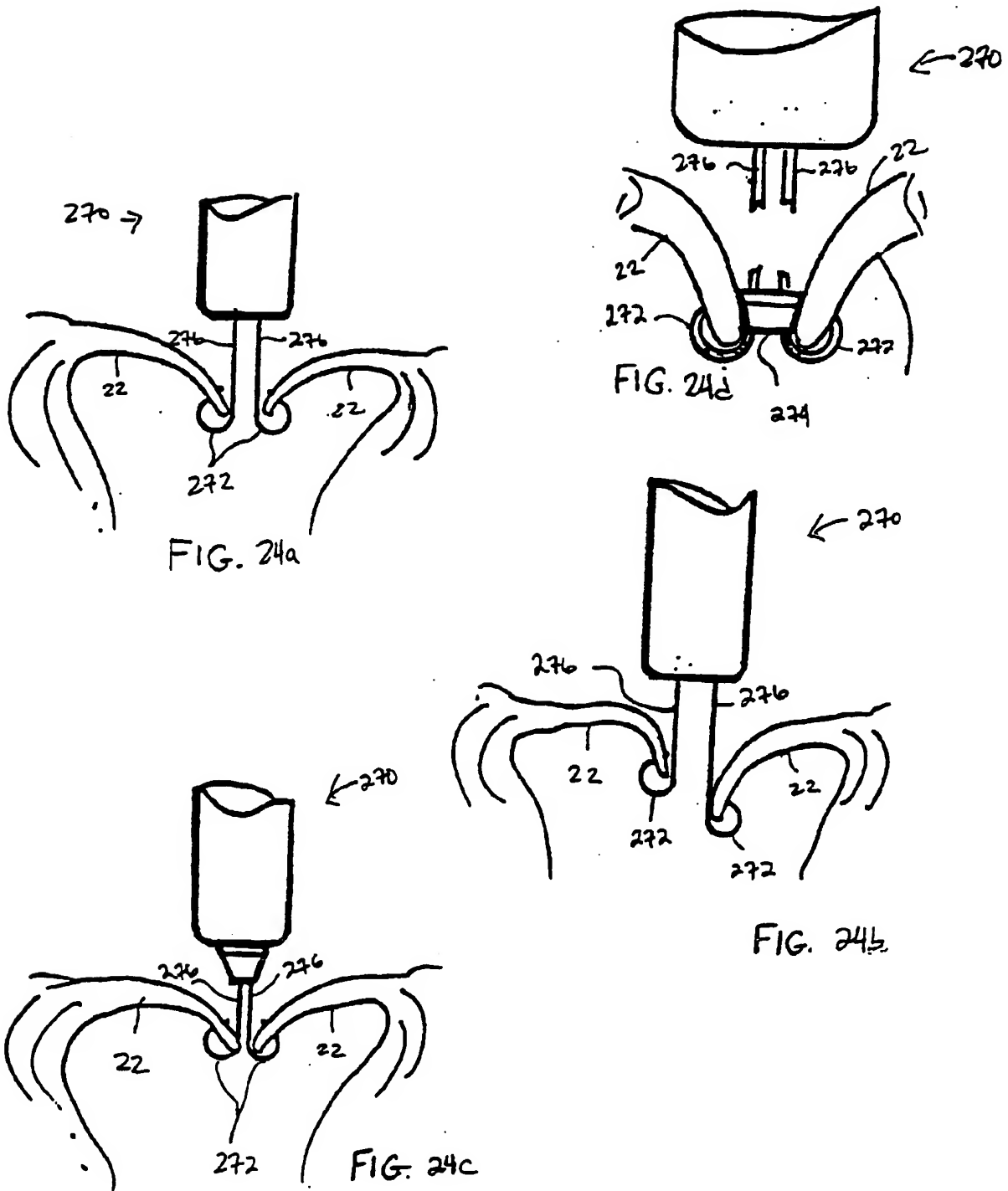


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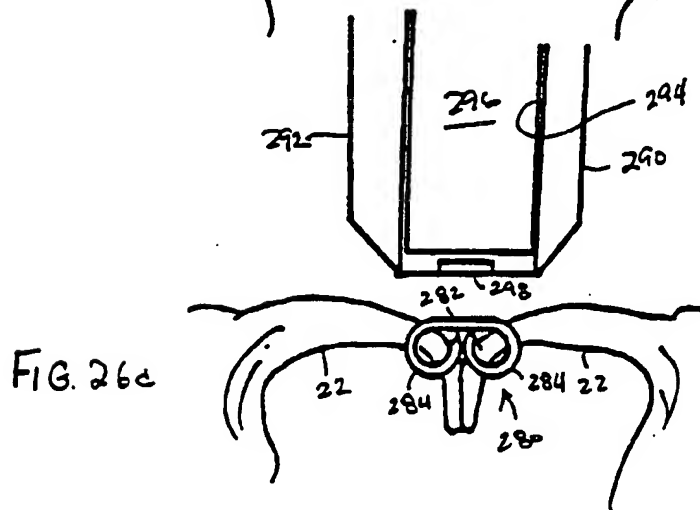
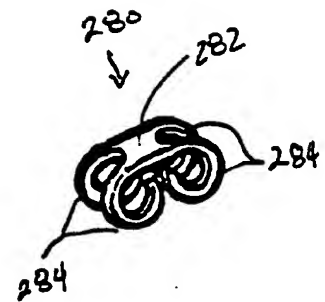
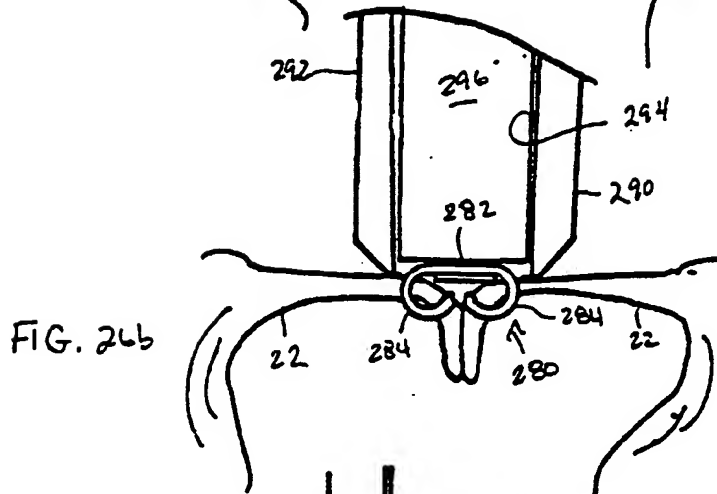
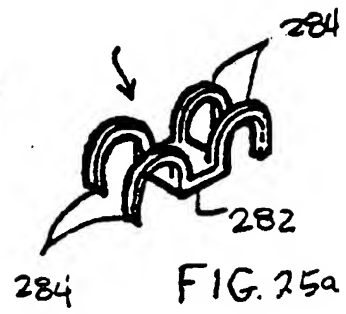
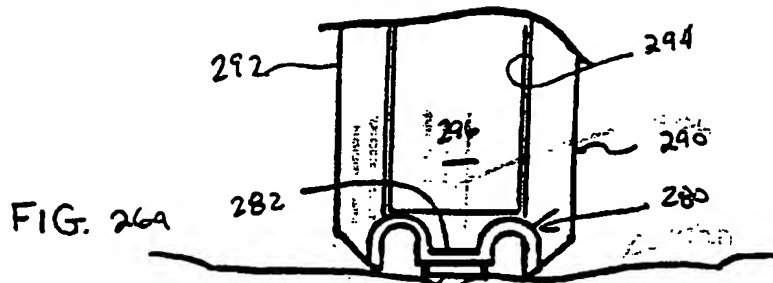
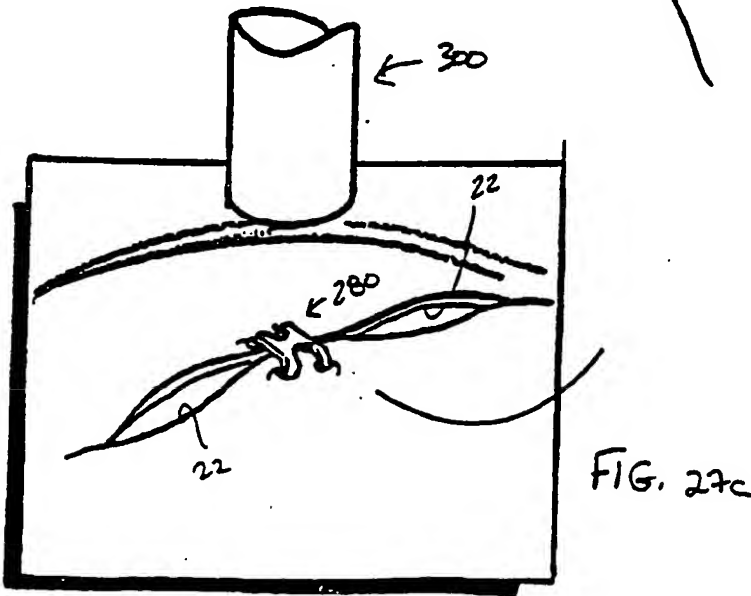
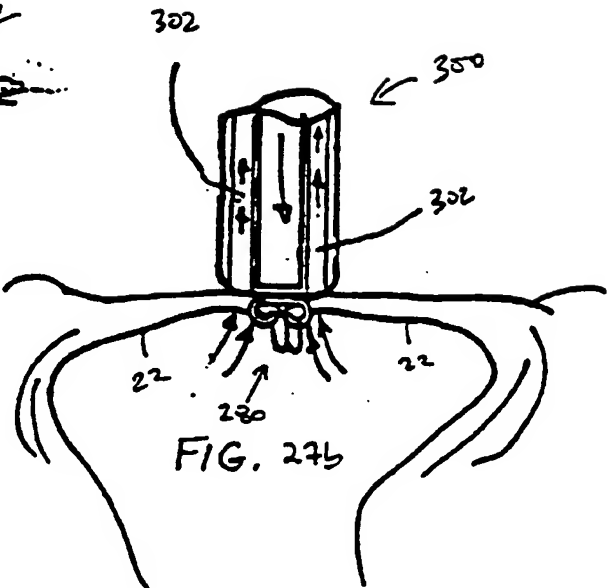
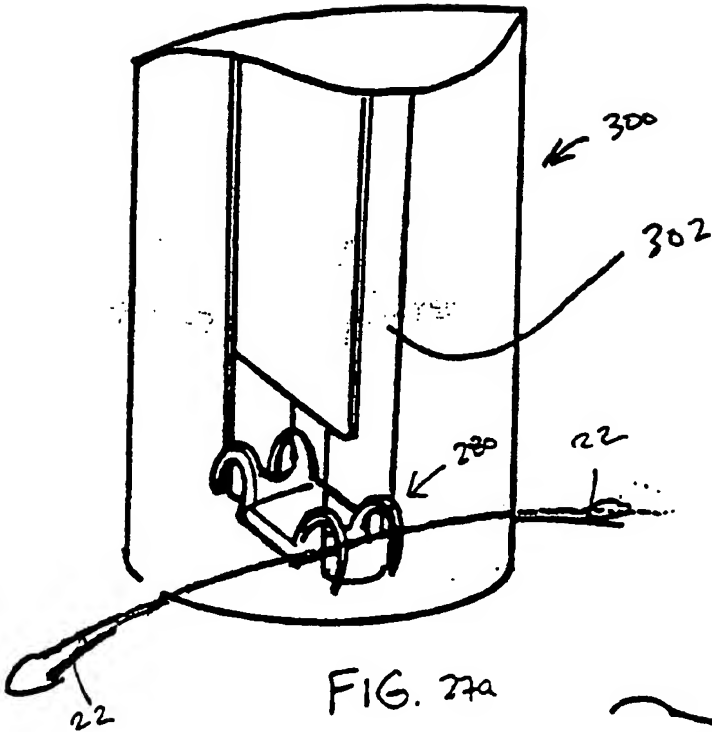
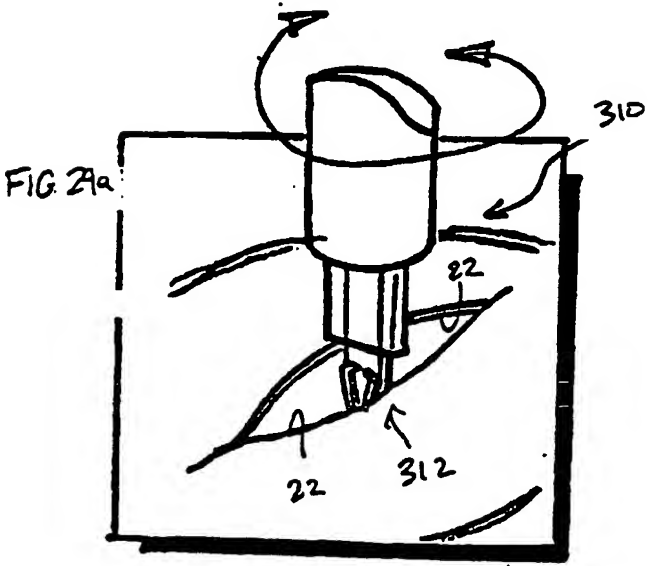
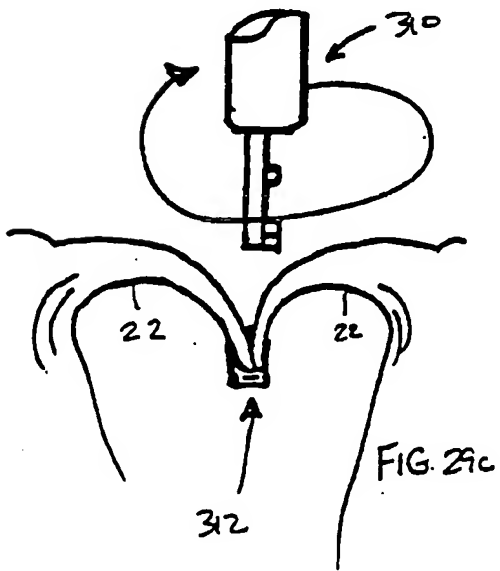
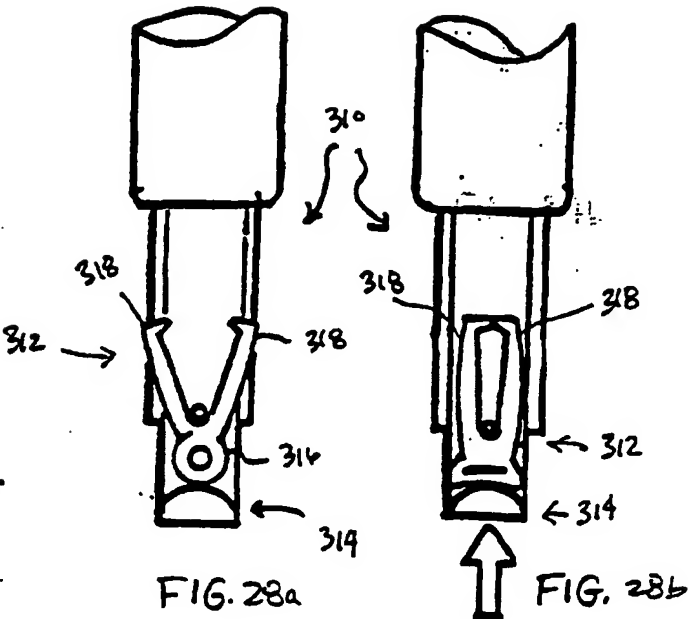
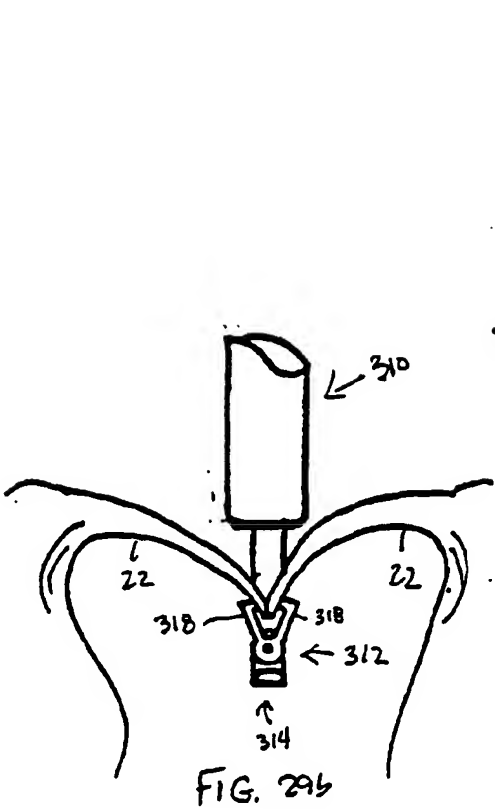


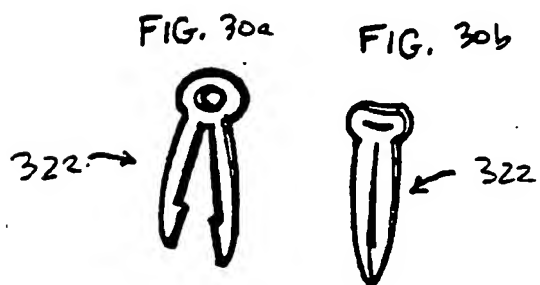
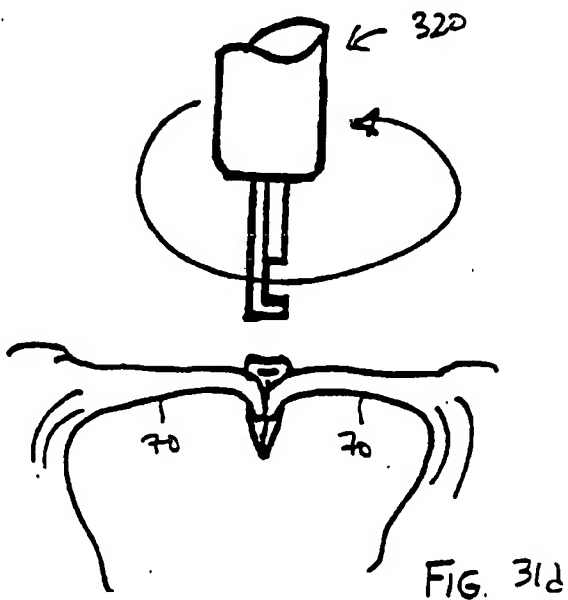
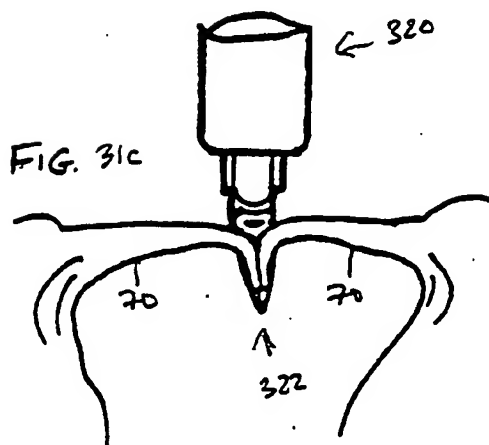
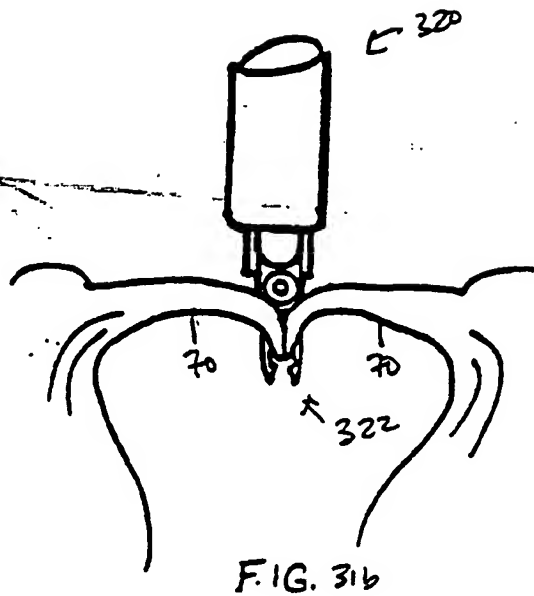
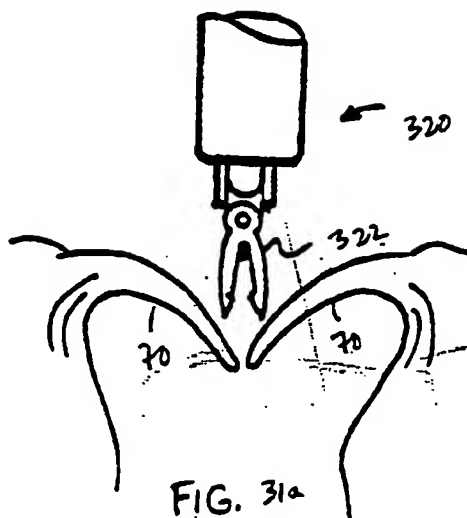
FIG. 25b

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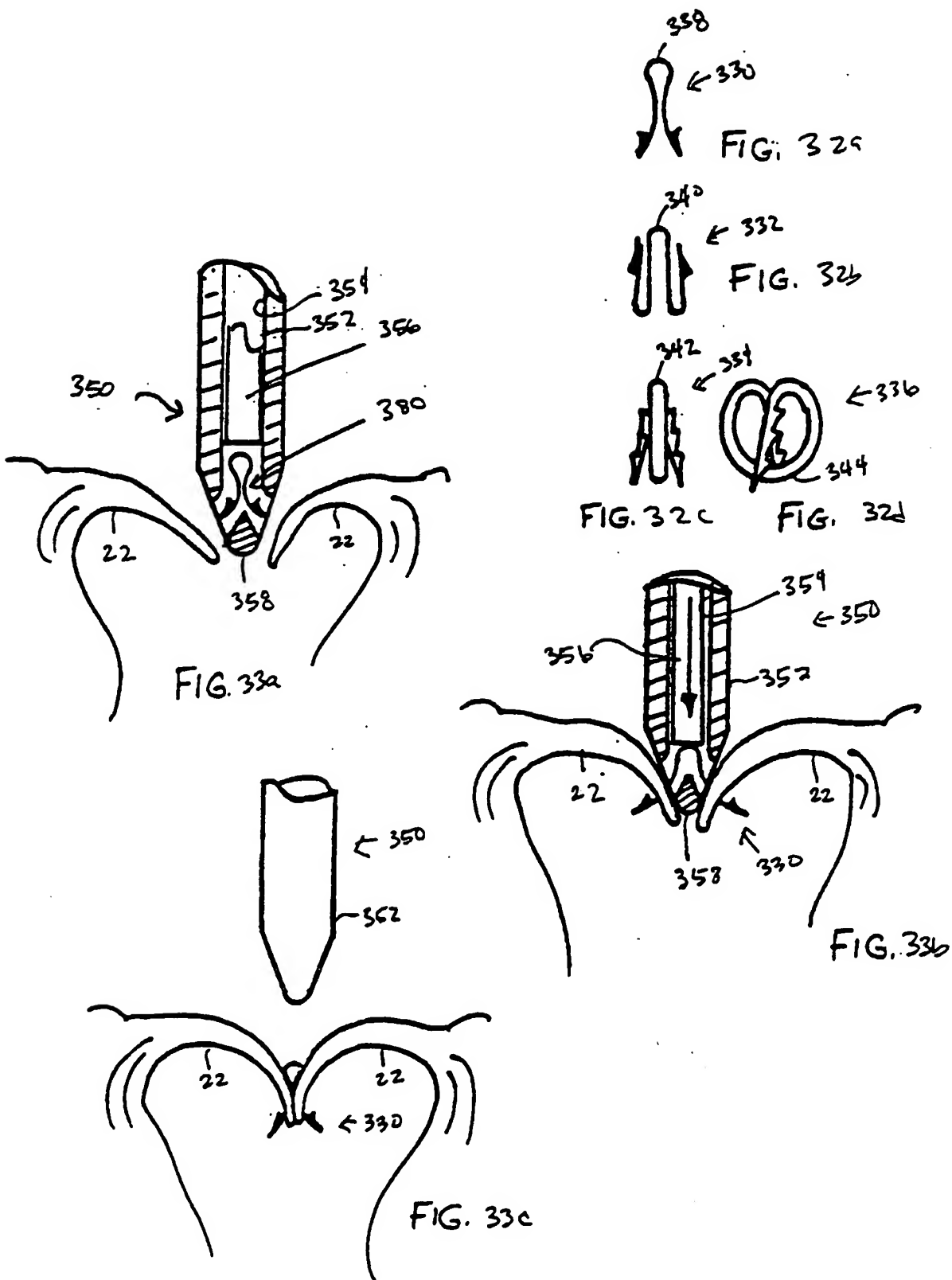




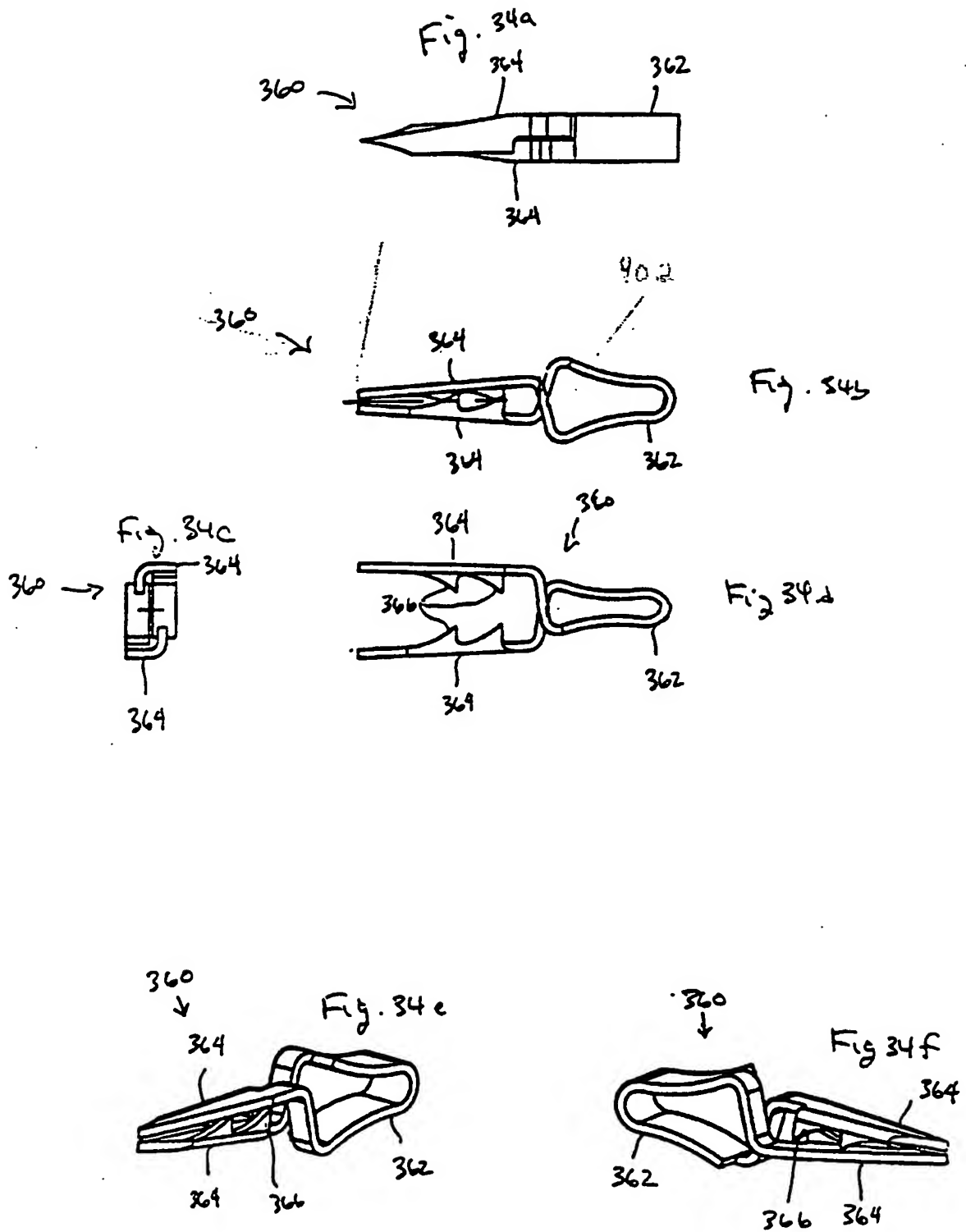
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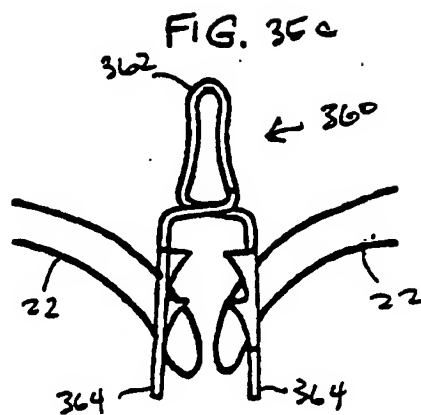
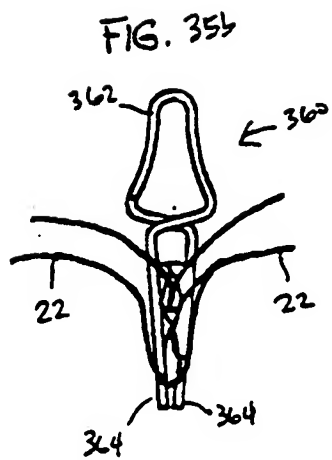
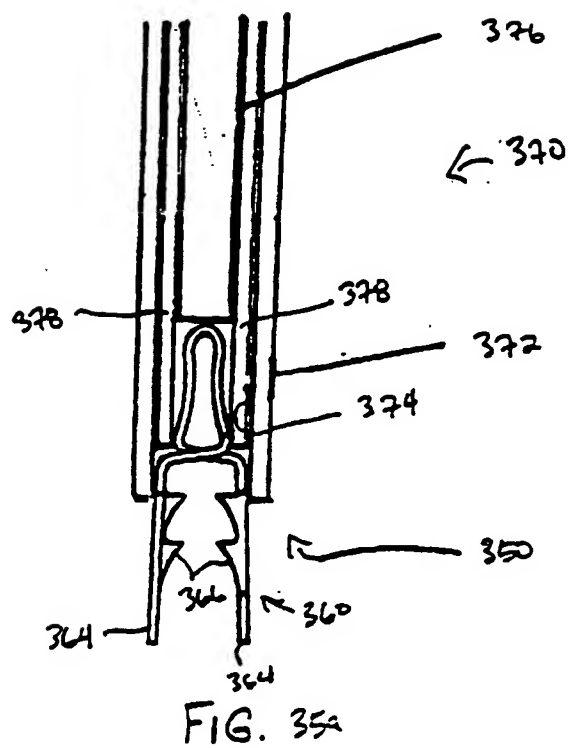
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Fig. 36a

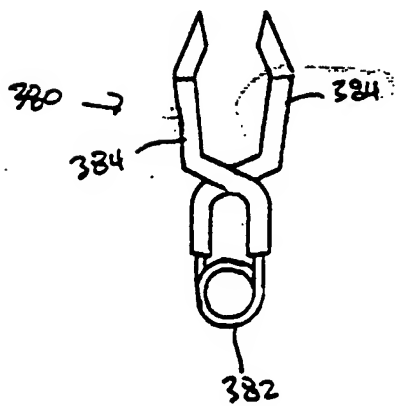


Fig. 36b

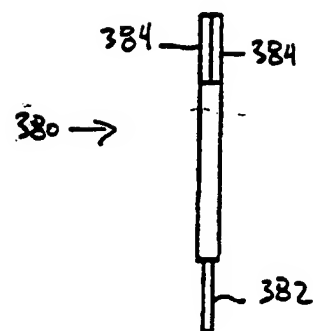


Fig. 36c

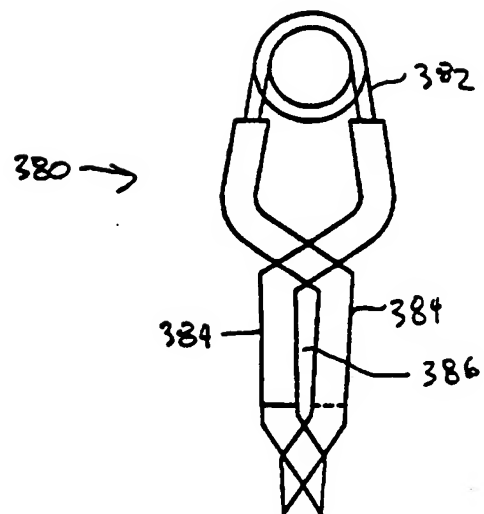


Fig. 37a

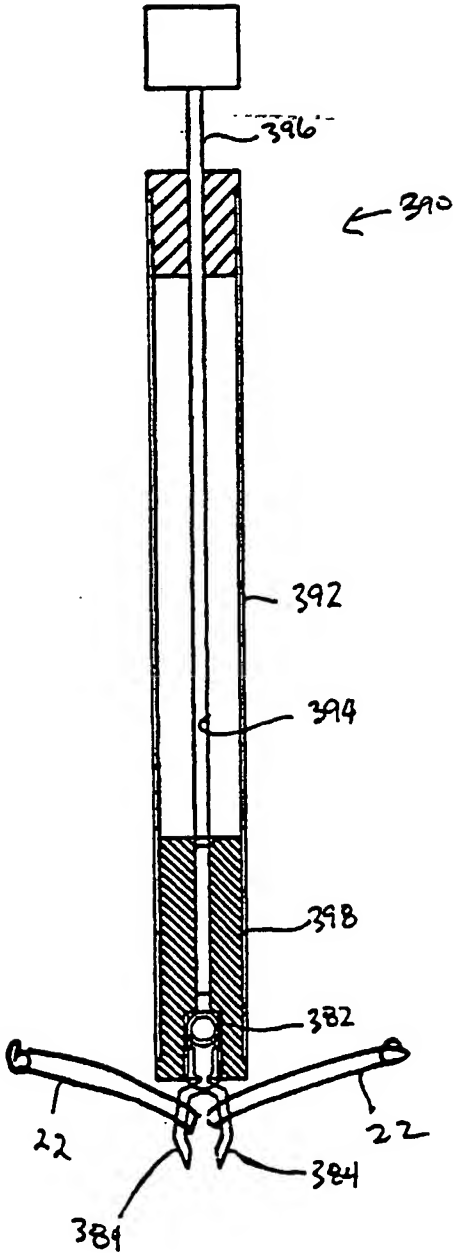
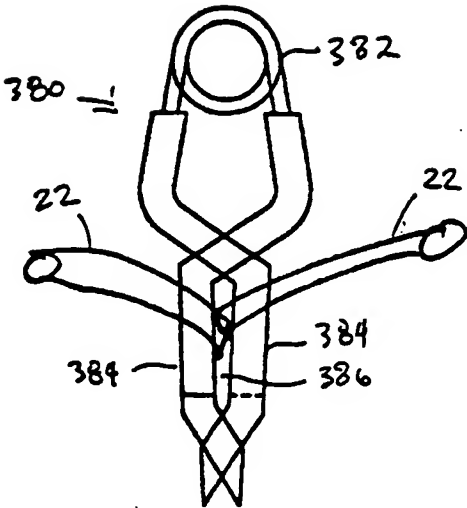


Fig. 37b



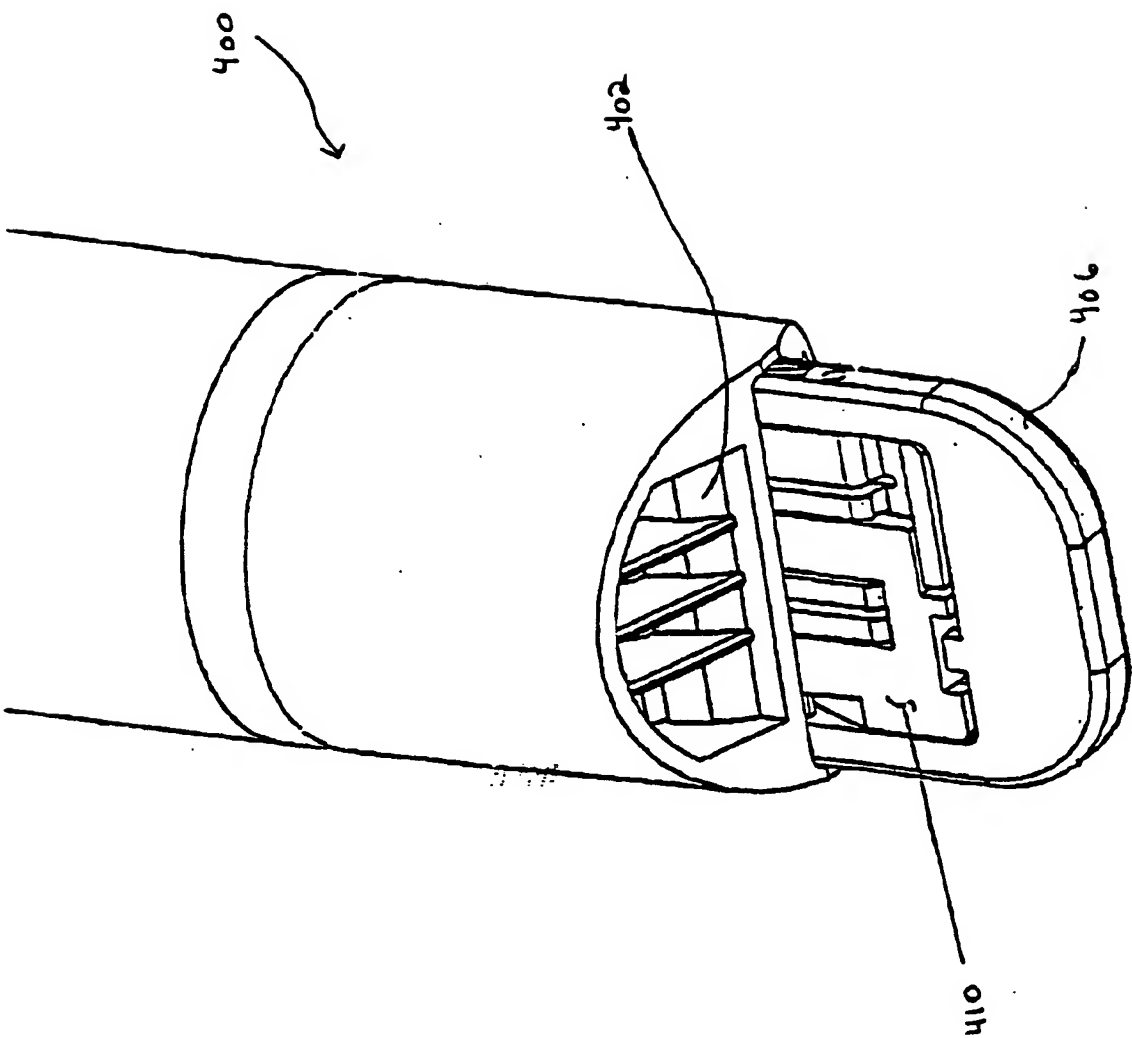
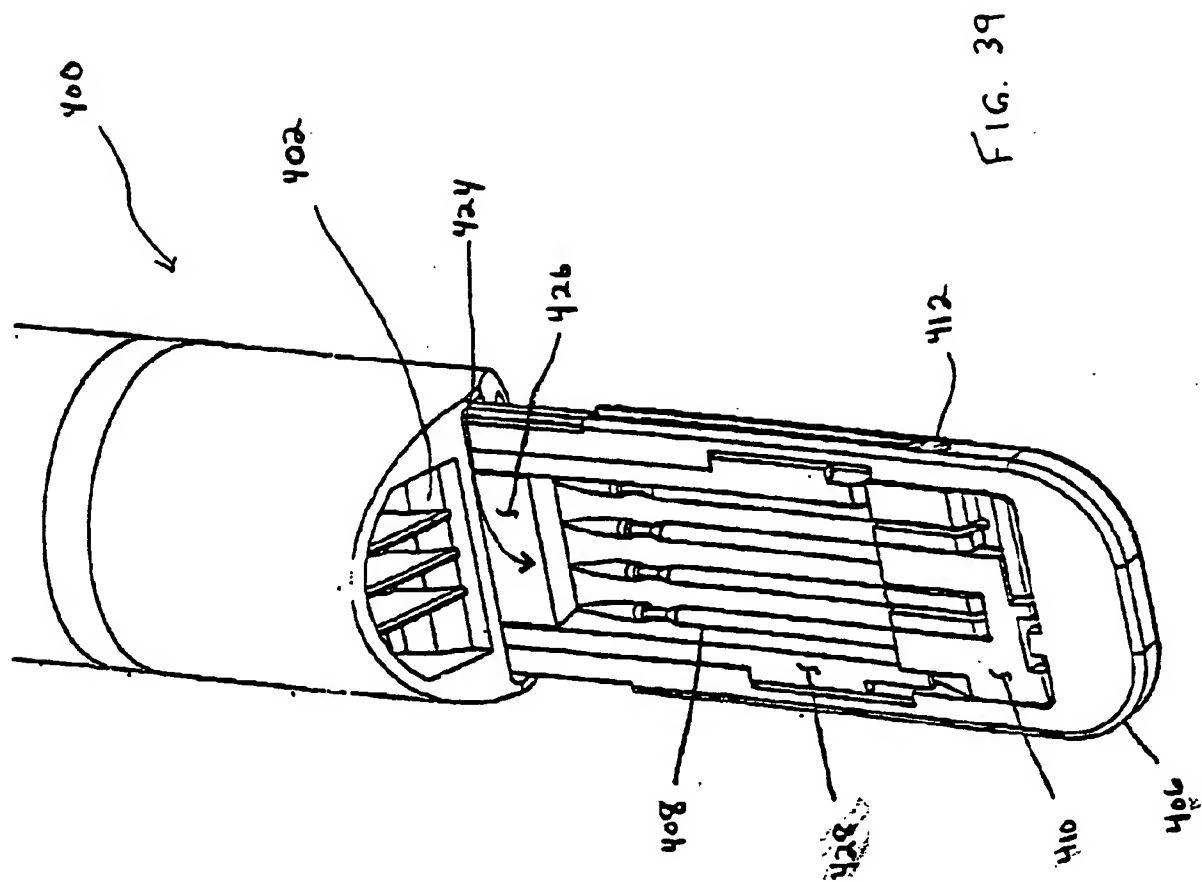


FIG. 38



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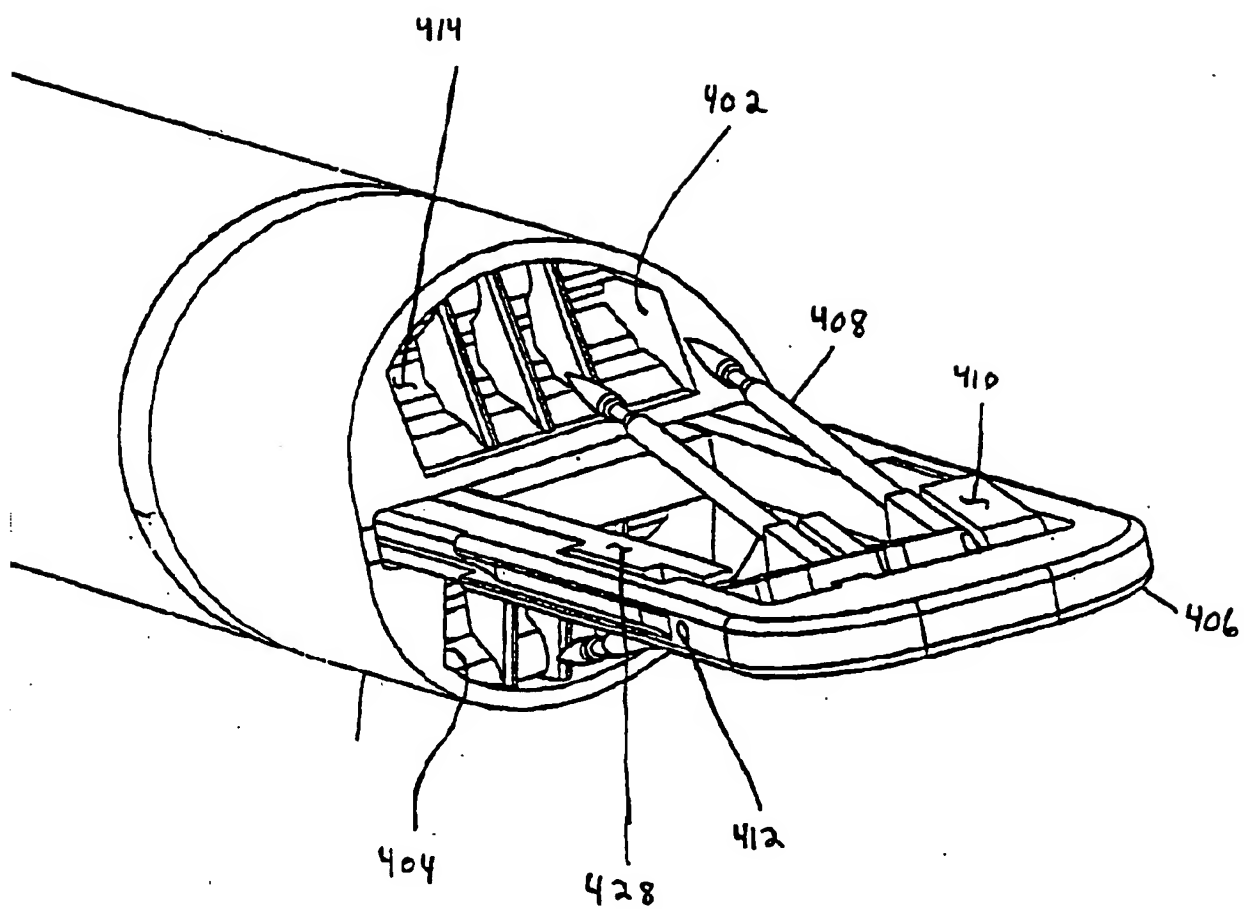
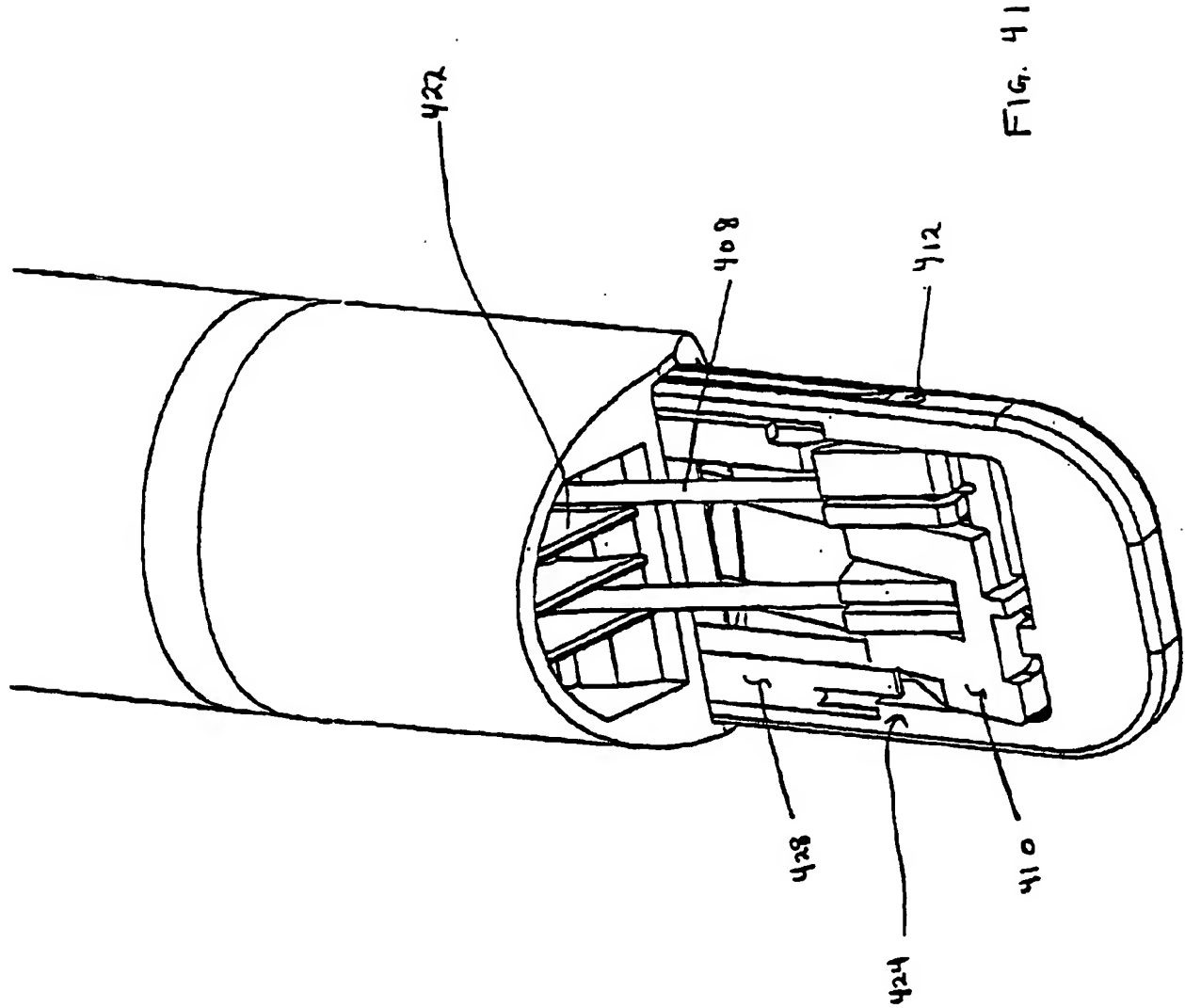


FIG. 40



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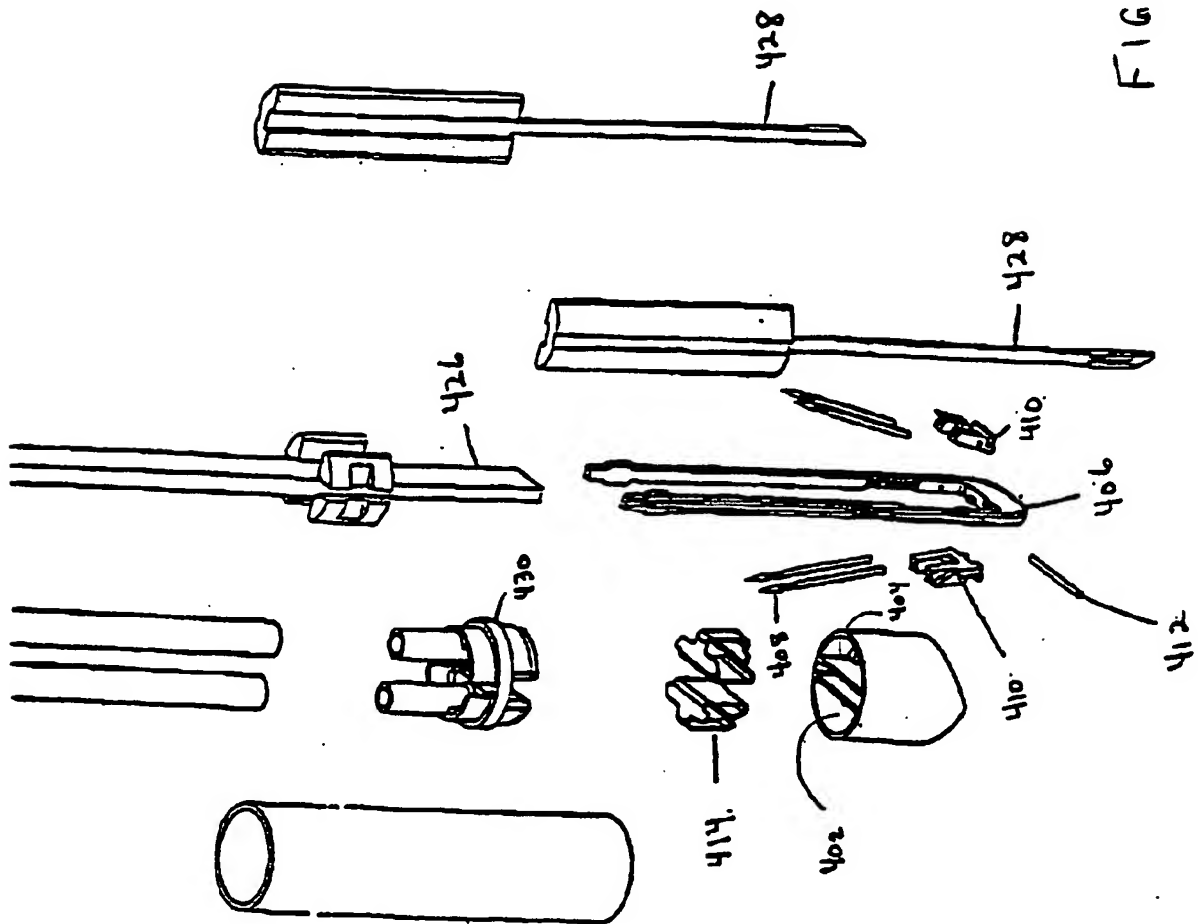


FIG. 42

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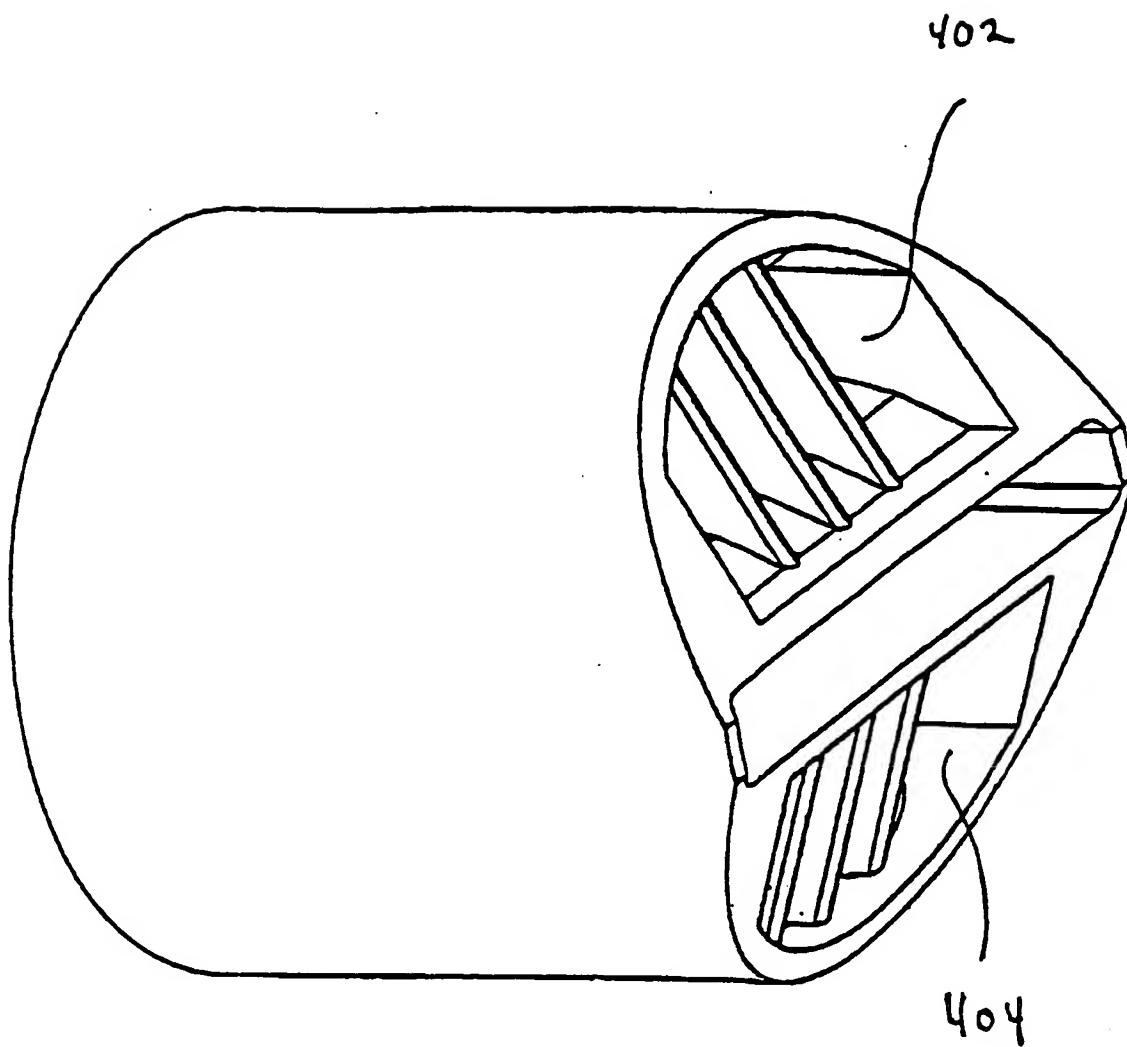
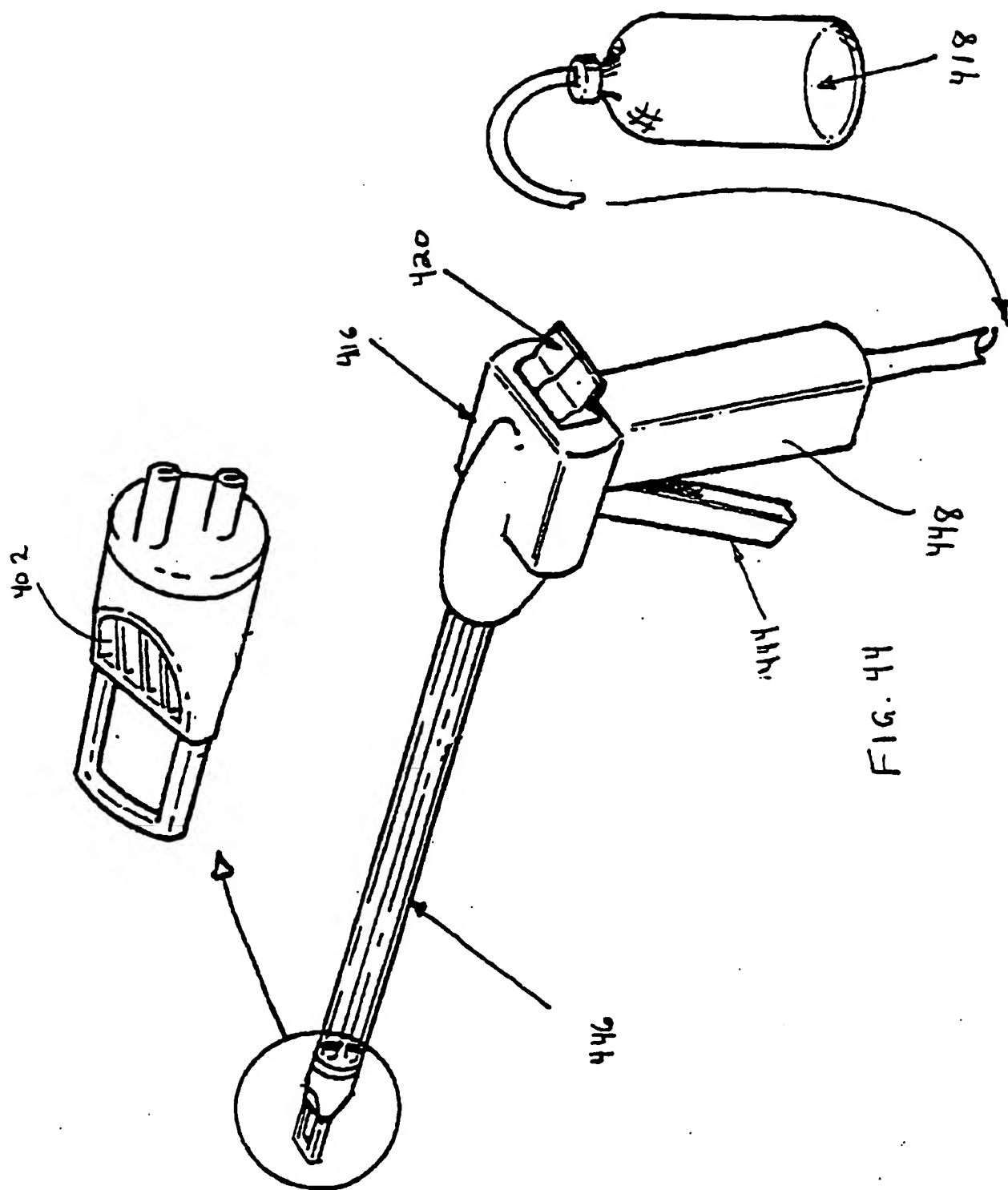


FIG. 43



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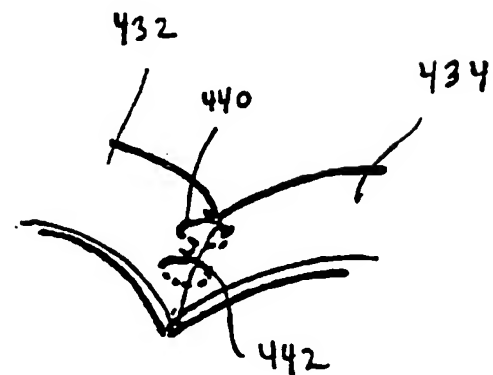
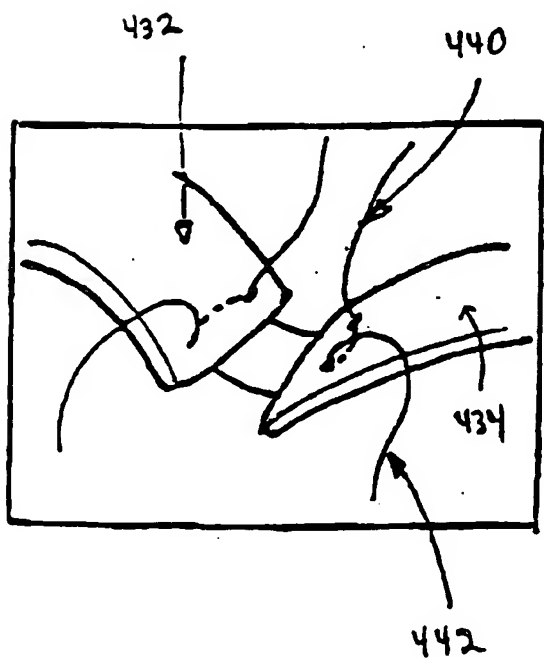
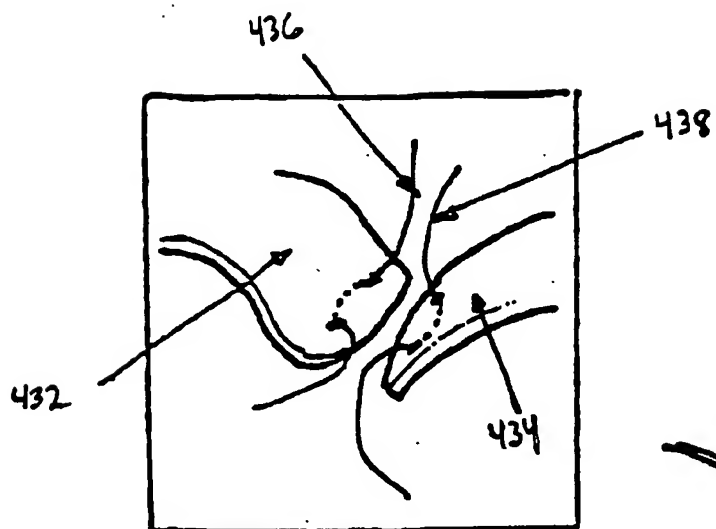


FIG. 45

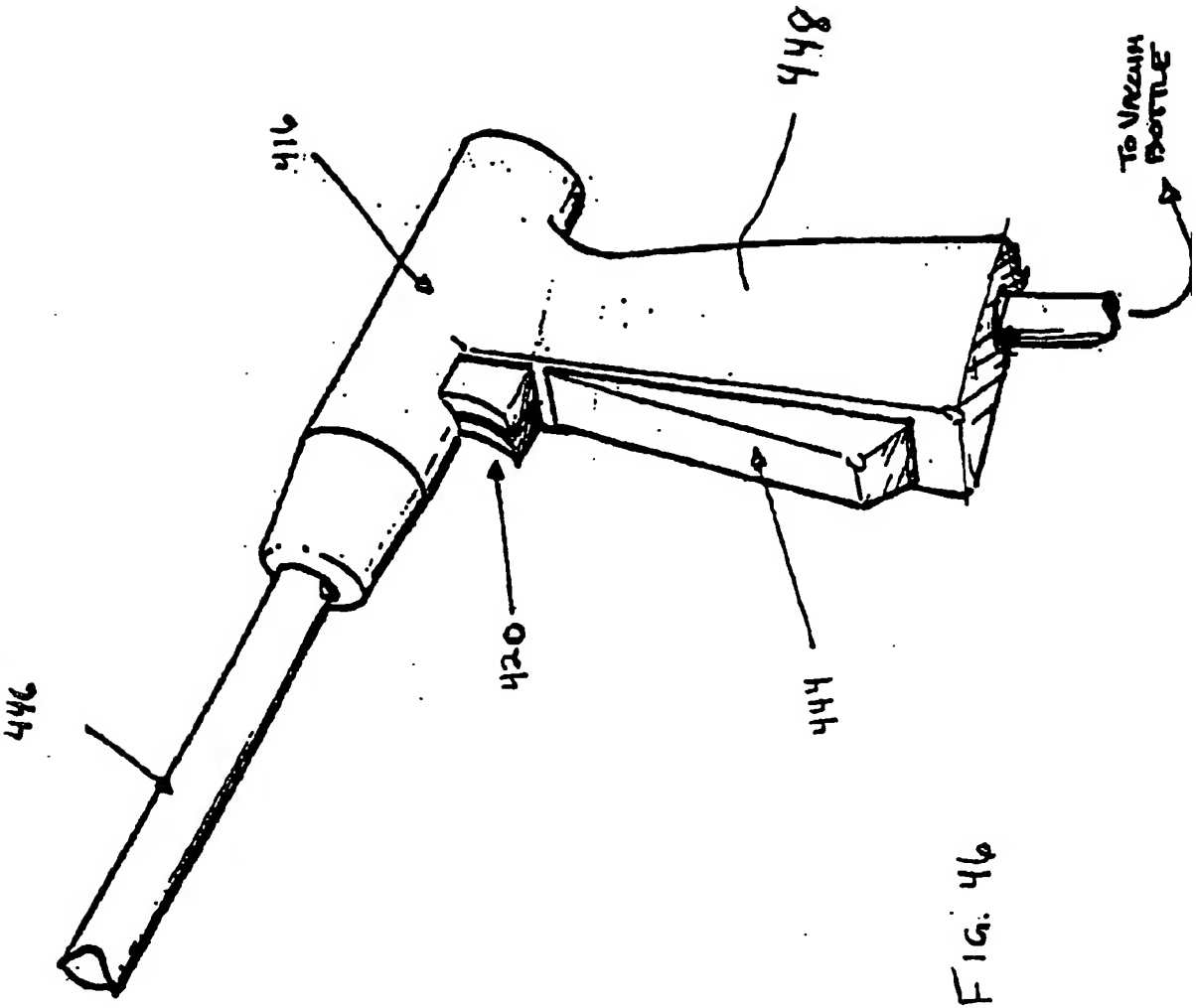


FIG. 46

## INTERNATIONAL SEARCH REPORT

 International Application No  
 PCT/US 00/29073

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/068 A61B17/00 A61B17/122 A61B17/064

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 768 324 A (SEGUIN JACQUES) 19 March 1999 (1999-03-19)	1,2,10, 14,16, 20,26, 30,32, 33, 37-44, 53,55-57
Y	the whole document	3-6,8,9, 34,36
X	DE 197 25 739 C (AESCULAP AG & CO.) 15 April 1999 (1999-04-15)	1,2,10, 20,26, 32,37, 40,43, 44,53,55
	column 3, line 30 - line 42; figures 1,2 -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Y	US 5 474 573 A (HATCHER) 12 December 1995 (1995-12-12) abstract; figures 5, 9 ---	3, 34
A	WO 99 00059 A (ALLEN WILLIAM ; LOTVIN ALAN (US); OZ MEHMET C (US); UNIV COLUMBIA ()) 7 January 1999 (1999-01-07) cited in the application  page 7, line 16 -page 8, line 27; figures 1-4 -----	1, 2, 20, 26, 32, 37, 40, 43, 44, 53, 55

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Information on patent family members

In International Application No

PCT/US 00/29073

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